INTERIM DRAFT

PCB RISK ASSESSMENT REVIEW GUIDANCE DOCUMENT

Prepared for

Fibers and Organics Branch
Chemical Management Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street
Washington, DC 20460

Prepared by

Versar Inc.
6850 Versar Center
Springfield, Virginia 22151

January 12, 2000

TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

APPENDICES

LIST OF TABLES

LIST OF FIGURES

1.0 INTRODUCTION

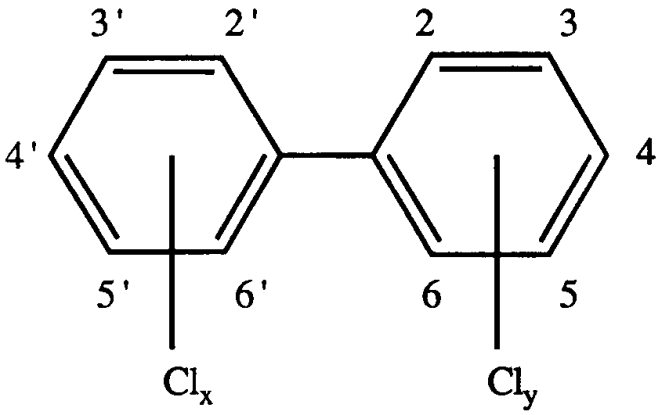
On June 29, 1998, the United States Environmental Protection Agency (U.S. EPA) amended its regulations for the control of polychlorinated biphenyls (PCBs) under the Toxic Substances Control Act (TSCA) (Federal Register Vol. 63, No. 124: p. 35384). Among other things, the rule provides risk-based disposal options for both PCB remediation and non-remediation wastes that will require the submission of risk assessments to EPA. (The PCB disposal rule is provided in Appendix A.) EPA will be required to make determinations with regard to the significance of the PCB risks at disposal sites, or from various disposal techniques, based on these assessments. To assist EPA headquarters and regional personnel in reviewing these PCB risk assessments, this guidance document has been prepared by EPA's Office of Pollution Prevention and Toxics (OPPT), National Program Chemicals Division (NPCD), Fibers and Organics Branch (FOB). Its purpose is to ensure that risk assessment reviews are conducted in a complete, consistent manner using a standardized format, and EPA-approved techniques and reference materials. Ultimately, the results of these reviews will be incorporated into the PCB Risk Assessment Review Data Base that is currently under development.

This PCB risk assessment review guidance document provides (1) background information on PCBs, including their uses, physical/chemical properties, potential for exposure, and toxicity; (2) an overview of the regulatory history and current status of PCB regulations; (3) fundamentals of exposure/risk assessment; and, most importantly, (4) guidance for reviewing PCB risk assessment documents. It also provides a copy of the template that may be used in the review of PCB risk assessment documents, as well as a list of acronyms that may appear in risk assessment documents, a glossary of risk assessment terms, and several appendices containing the PCB disposal rule and relevant excerpts from key EPA risk assessment guidance documents. This guidance document is not intended to instruct the reader in all aspects of risk assessment, but rather to provide an overview of risk assessment techniques, and general guidance for reviewing PCB risk assessments that is consistent with standard EPA risk assessment methodologies. This guidance document will be modified, as needed, based on changes in risk assessment methodologies, standard assumptions used to assess exposure or toxicity, or other factors that will result in changes in the way EPA will review risk assessments related to PCB disposal under TSCA. Revised version of this document will be posted at EPA/PCB homepage (www.epa.gov/pcb).

2.0 BACKGROUND ON PCBS

2.1 Definition and Chemical Structure

PCBs are a class of compounds characterized by a biphenyl structure (i.e., 2 carbon rings joined by a chemical bond at a carbon atom on each ring) to which one to ten chlorine atoms are attached. The positions on the carbon rings where the chlorines are attached are said to be "chlorine substituted". The general structure of a PCB molecule is presented below in Figure 1.



X = 1 to 5, Y = 1 to 5, X + Y $\geq$ 1

Figure 1. General Chemical Structure of PCBs

There are a total of 209 possible PCB congeners, based on the various combinations of numbers of chlorine substitutions (mono- through deca-chlorinated) and their positions on the biphenyl molecule (see numbering scheme for the carbon atoms on the biphenyl molecule in Figure 1). Congeners with the same number of chlorine atoms, but in different positions, are termed isomers.

The 209 PCB congeners are also known by their International Union of Pure and Applied Chemists (IUPAC) numbers. Some of the PCB congeners that are of greatest concern, based on their potential for toxicity and their occurrence in environmental samples, and their IUPAC numbers are listed in Table 1 (U.S. EPA, 1996).

PCB congener mixtures have been produced by a variety of manufacturers throughout the world, and are thus known by various trade names. In the United States, PCBs have been manufactured primarily by the Monsanto Corporation, and were marketed under the trade name Aroclor (ATSDR, 1996). The primary Aroclors were: 1016, 1221, 1232, 1242, 1248, 1254, 1260, and 1268. The last two digits of this numbering system are indicative of the chlorine content, by percent, of the mixture. For example, Aroclor 1242 is a mixture of the mono- through hepta-chlorinated PCB congeners with an average chlorine content of 42 percent. Germany marketed PCBs under the name Clophen, and Japan used the name Kanechlor. The numbering schemes for these products are different than for the Aroclors. PCBs have also been marketed under the names Fenclor (Italy) and Phenoclor (France) (ATSDR, 1996). Table 2 presents some of the commercial PCB mixtures and their chlorine contents (U.S. EPA, 1996).

2.2 PCB Production and Use

PCB mixtures have been used in many industrial applications. Because of their insulating properties, chemical stability, and relative inflammability, they have been found to be particularly useful as coolants and lubricants, and have been widely used in capacitors, transformers, and other electrical equipment. Other applications have included use in plasticizers, surface coatings, inks, adhesives, flame retardants, pesticide extenders, paints, and carbonless duplicating paper (ATSDR, 1996).

PCBs were produced in the United States between 1929 and 1977, with production peaking in 1970 with a volume of 39,000 metric tons (Versar, 1976). The estimated cumulative production and consumption volumes of PCBs in the United States from 1930 to 1975 were 635,000 metric tons produced; 1,400 metric tons imported (primarily from Japan, Italy, and France); 568,000 metric tons sold in the United States; and 68,000 metric tons exported (Versar, 1976). Regulations issued by EPA beginning in 1977, principally under TSCA, strictly limited the production, import, use, and disposal of PCBs. Although the manufacture of PCBs has been discontinued in the United States, these mixtures remain in the environment from previous releases. They also continue to exist in some types of older capacitors, appliances, light ballasts, and various other materials.

2.3 Environmental Releases and Background Concentrations of PCBs

Subsequent to the 1977 ban on the production and use of PCBs in open systems, releases of commercially produced PCBs to the environment (aside from minimal releases occurring during approved disposal and/or destruction) have been limited to accidental releases of in-service PCBs (U.S. EPA, 1987a). Accidental releases are the result of leaks or spills during failure/breakage of an

existing piece of PCB-containing equipment, or incomplete combustion occurring during accidental fires involving PCB-containing equipment. As indicated in Table 3, direct releases of PCBs to air, water, and land have been limited. However, a large amount of PCBs has been transferred off site for the purposes of treatment/disposal (Table 4). For example, a total of over 460,000 kg of PCBs were transferred for treatment/disposal during 1993 (U.S. EPA, 1993; U.S. EPA, 1995a).

Currently, a major source of PCB releases to air, water, and soil occurs from the cycling of PCBs remaining in the environment from one medium to another (ATSDR, 1996). This cycling process involves volatilization of PCBs from aquatic and terrestrial surfaces into the atmosphere, and then subsequent redeposition of these compounds onto the Earth's surfaces (ATSDR, 1996). Typical mean PCB concentrations are 1 to 10 ng/m^3, 0.6 ng/m^3, and <0.1 ng/m^3 in air from urban, rural, and remote locations, respectively; <100 μg/kg in background soils; <0.1 μg/L in drinking water; 0.5 to 3.3 ng/L in Great Lakes water; and 0.5 μg/g in freshwater fish (ATSDR, 1996).

2.4 Physical/chemical Properties and Fate

Physical, chemical, and biological processes influence the fate and transport of PCBs in the environment. The tendencies and rates at which these processes occur depend on the physical and chemical properties of individual PCBs and their mixtures and site-specific environmental conditions. Important fate and transport processes include, but may not be limited to, the following:

- Physical loss processes, such as sorption and volatilization;
- Transport processes, such as dilution, advection, and dispersion;
- Chemical processes, such as hydrolysis, photolysis, acid-base reactions, and ion pairing or complexes; and
- Degradation by aerobic and anaerobic microbiological processes.

Table 5 summarizes some of the key physical and chemical properties of PCB Aroclors that affect their fate in the environment. These properties include water solubility, vapor pressure, Henry's Law Constant, organic carbon distribution coefficient (K_{oc}), and octanol-water partition coefficient (K_{ow}).

Water solubility is the maximum concentration of a chemical that can result when that chemical is dissolved in water at a specified temperature. In general, chemicals with high water solubility values are more readily dispersed throughout the nonlipid components of the environment

than chemicals with low water solubility values. Chemicals with high water solubility tend to be mobile in soil, sediment, and groundwater. Vapor pressure is the pressure exerted by a chemical vapor in equilibrium with its solid or liquid form at any given temperature. The higher the vapor pressure, the more likely a chemical is to exist in a gaseous state. Henry's Law constant is the ratio of vapor pressure to solubility and is indicative of the propensity of a chemical to volatilize from surface water (Lyman et al., 1982). The larger the value, the more likely the chemical will volatilize. K_{oc} is a measure of the tendency for organic chemicals to be adsorbed to soil and sediment. Organic chemicals with relatively high values of K_{oc} (i.e., greater than 1,000 ml/g) are likely to be adsorbed to organic carbon in soils to an appreciable extent. K_{ow} provides a measure of the extent of a chemical partitioning between water and octanol at equilibrium. K_{ow} is often used as an indication of a chemical's affinity for lipid soluble materials. The higher the value, the more likely a chemical will partition to lipophilic materials.

As indicated by the water solubility and K_{ow} values listed in Table 5, PCBs are relatively insoluble in water, and congeners with higher chlorine content tend to be more insoluble (U.S. EPA, 1996). In contrast, PCBs are highly soluble in biological lipids, and have been found to accumulate in animal and human tissues. The bioconcentration factors (BCFs) (i.e., the ratio of the PCB concentration in aquatic organisms to the chemical concentration in water at equilibrium) for PCBs range from 26,000 to 660,000 (ATSDR, 1996). The K_{oc} values for PCBs indicate that they adsorb readily to organic materials such as sediments and soils, with adsorption increasing with the chlorine content of the mixture and the organic content of the environmental media. Although PCBs have relatively low vapor pressures, they are likely to volatilize into the atmosphere, particularly from water; congeners with lower chlorine contents are more volatile. Biodegradation (i.e., dechlorination) is slow, as are other breakdown processes (i.e., photolysis, and chemical degradation) (U.S. EPA, 1996). For example, the half-life of PCBs in soil is several years (ATSDR, 1996). Transformation processes in water and air range from < 1 day to 210 days, depending on the chlorine substitution pattern and the environmental conditions (ATSDR, 1996). As a result, PCBs are widespread in the environment; they have been detected in many types of environmental media, including air, water, sediment, soil, and foods.

2.5 Potential for Exposure

Evidence of widespread exposure to PCBs is indicated by the detection of PCBs in blood, adipose tissue, and breastmilk of the general population of the United States (Schecter, 1991). Humans may be exposed to PCBs via inhalation of PCB-contaminated air, dermal contact with PCBs in soil or other media, and ingestion of water, food, or soil containing PCBs. Ingestion of PCB-contaminated fish has been considered a primary source of human exposure in locations where fish

consumption (i.e., sports and subsistence fishermen) and PCB contamination are higher than for the general population. A related potentially highly exposed population is breast-fed infants of mothers who consume large amounts of PCB-contaminated fish. Also, individuals residing near PCB-containing waste sites may have relatively higher exposures than the general population. Another potentially highly exposed population is occupational groups who may come into contact with PCB-contaminated media. Occupational exposures may occur via inhalation, dermal contact, or incidental ingestion of PCB residues from contact with contaminated materials in the workplace (i.e., waste site cleanups, or disposal activities), during repair and maintenance of electrical equipment containing PCBs, or from accidents or fires involving PCBs (ATSDR, 1996).

2.6 Toxicity

Epidemiological data on the health effects of PCBs in humans and the results of animal toxicity tests provide information about the toxicity of PCBs. The evaluation of the health effects of PCB mixtures is complicated by their complex congener composition (ATSDR, 1996). However, certain generalizations can be made about PCBs to which humans may be exposed in the environment.

Observed effects in humans have ranged from mild reactions to serious health consequences. Occupational studies have indicated that skin irritations (i.e., acne and other rashes) can occur from dermal contact with PCBs, and irritations of the nose and lung can occur from inhalation exposures (ATSDR, 1996). Serious health effects occurred in individuals exposed via contaminated rice oil in Yusho, Japan. However, the effects of these exposures have been attributed primarily to high levels of polychlorinated dibenzofuran (PCDF) contaminants in the PCB-contaminated rice oil (ATSDR, 1996). In experimental animals orally exposed to PCBs, liver, stomach, and thyroid gland damage, as well as anemia, acne, and reproductive effects have been observed (ATSDR, 1996). Dermal exposure studies in rabbits produced liver, kidney, and skin damage, while inhalation studies in rats have indicated kidney damage (ATSDR, 1996). For further information regarding the results of toxicity studies in animals, refer to ATSDR (1996).

EPA has classified PCBs as a possible human carcinogen. The results of occupational studies in humans have provided inconclusive evidence of cancer effects. However, animal studies have shown that the higher chlorinated mixtures (e.g., Aroclor 1260) can be hepatocarcinogens. More recent studies have shown that all PCB mixtures pose a cancer hazard, but that different PCB mixtures vary in potency (U.S. EPA, 1996).

Several PCB congeners are considered to be dioxin-like in terms of their toxicity. Toxicity equivalency factors (TEFs) that relate these congeners to the toxicity of 2,3,7,8-tetrachloro-dibenzo-p-dioxin (TCDD) (the most toxic of the polychorinated dibenzo-p-dioxins (PCDD) and PCDFs) have been developed, and are presented in Table 6. Toxicity equivalency concentrations (TEQs) are calculated as the product of the PCB concentration times the TEF. In addition, PCBs have been found to contain PCDDs and PCDFs in varying, but low, concentrations (U.S. EPA, 1994a).

3.0 OVERVIEW OF REGULATORY HISTORY AND CURRENT STATUS OF PCBS

3.1 TSCA Provisions

Under TSCA, Section 6(e), the Environmental Protection Agency is required to regulate and control chemicals in commerce that are found to result in "unreasonable risks to human health and the environment." As a result of evidence that indicated that PCBs cause harmful effects and are persistent in the environment, domestic manufacture of PCBs was halted under TSCA in 1977. However, PCBs have been found in many environmental matrices (i.e., air, water, soil, sediment, foods, animal tissues) from previous releases, and some PCBs remain in use. For example, consumer products such as fluorescent light ballasts, older electrical devices or appliances, hydraulic fluids, and old microscope oil may contain PCBs (ATSDR, 1996). PCBs have also been found in insulation, roofing and siding materials, certain types of adhesive tapes, and paint (U.S. EPA, 1994b).

3.2 PCB Policies

On April 2, 1987, EPA published its PCB Spill Cleanup Policy (U.S. EPA, 1987b) which may be found at 40 CFR Part 761, Subpart G. The Policy established requirements for the cleanup of spills resulting from the release of materials containing PCBs at concentrations of 50 ppm or greater that occur after the effective date of the rule (i.e., May 4, 1987). Under the Policy, spills exceeding 10 pounds of PCBs; spills which directly contaminate surface water, drinking water, or sewers; and spills that directly contaminate grazing land and vegetable gardens must be reported to the appropriate EPA regional office. Spills of low concentration PCBs (i.e., <500 ppm) must be cleaned up as follows: solid surfaces must be cleaned to 10 μg/100 cm^2, as verified by standard wipe tests; soil in the spill area must be excavated and the ground must be covered with clean soil containing <1 ppm PCBs. High concentration spills (i.e., >500 ppm PCBs) must be reported to the EPA regional office. High concentration spills in outdoor electrical substations must be cleaned as follows: solid surfaces must be cleaned to 100 μg/100 cm^2, as measured by wipe test; and soil must be cleaned to 25 or 50 ppm, depending on the circumstances. High concentration spills in other restricted access areas must be cleaned up as follows: high contact solid surfaces must be cleaned to 10 μg/100 cm^2, and low contact indoor surfaces must be cleaned to 10 μg/100 cm^2 or 100 μg/100 cm^2 and encapsulated. Low contact outdoor surfaces must be cleaned to 100 μg/100 cm^2 and soil must be cleaned to 25 ppm. For non-restricted access areas (e.g., residences), contaminated furnishings and toys should be disposed, and indoor solid surfaces should be cleaned to 10 μg/100 cm^2. Outdoor non-restricted areas should be cleaned to 10 μg/100 cm^2 or 100 μg/100 cm^2, depending on the circumstances, and soil should be cleaned to 10 ppm.

3.3 PCB Disposal Rule

On December 6, 1994, the United States Environmental Protection Agency (U.S. EPA) proposed amendments to the regulations under TSCA for the control of polychlorinated biphenyls (PCBs). After a period of public comment, and revisions to the proposed rule, the rule was finalized and published on June 29, 1998. The rule provides authorizations for certain uses of PCBs, authorizes the manufacturing, processing, and distribution in commerce of PCBs for use in research and development activities; specifies additional alternatives for cleanup and disposal of PCBs; and clarifies the processing and disposal exemption. It also establishes procedures for disposing of remediation waste standards for decontamination, controls for storage for reuse, and provides a mechanism for coordinating TSCA disposal approvals among various Federal programs.

The final rule also allows the EPA Regional Administrator, on a case-by-case basis, to make a finding that spills, leaks, or other uncontrolled discharges from a pre-1978 disposal site constitutes unreasonable risk of exposure to PCBs. If this finding is made, the owner or operator may clean up the site in accordance with the Spill Cleanup Policy, if applicable, or in accordance with 761.61. Section 761.61 (PCB remediation waste) provides three options for disposal of such waste. These include the use of (1) the self-implementing disposal, which is similar to the Spill Cleanup Policy; (2) an existing approved disposal technology; and (3) the risk-based disposal option. The self-implementing option specifies cleanup levels for non porous surfaces of 10 μg PCBs/100 cm^2 for high occupancy areas, and 100 μg PCBs/100 cm^2 for low occupancy areas; cleanup levels for bulk remediation wastes are 1 ppm in high occupancy areas, and 25 ppm for low occupancy areas. Under the risk-based option (761.61(c)), the EPA Regional Administrator could approve different cleanup levels, based on a site-specific risk assessment.

The rule also provides options for disposal of non-remediation, PCB bulk product wastes at Section 761.62. These wastes are defined as those with concentrations $\geq$50 ppm, when taken out of service. There are four options, specified in the rule, for the disposal of these wastes: (1) performance-based disposal; (2) disposal in solid waste landfills; (3) risk-based disposal; and (4) disposal as daily landfill cover or roadbed. The performance-based option includes several disposal options, such as disposal in RCRA Subtitle D landfills, TSCA chemical waste landfills, and thermal decontamination. Bulk waste may be disposed of in solid waste landfills, if it meets certain criteria (i.e., if the PCBs are tightly bound in the matrix of the waste and leach <10 μg/liter; or if the waste is automobile and appliance shredder fluff that does not contain PCB small capacitors). Under the risk-based option (761.62(c)), EPA will evaluate applications for storage and disposal of PCB bulk product wastes on a case-by-case basis to determine whether a proposed method would result in unreasonable risks to human health.

The risk-based options provided at 761.61(c) for remediation wastes, and at 761.62(c) for non-remediation PCB bulk product waste, will require that PCB risk assessments be prepared and submitted to EPA Regional Administrators for review. These risk assessments will need to reviewed for adequacy and consistency with Agency policies. Thus, the following sections of this document provide an overview of risk assessment techniques, and guidance for reviewing risk assessment documents submitted under the final PCB disposal rule.

4.0 FUNDAMENTALS OF RISK ASSESSMENT: AN OVERVIEW

4.1 Definition of Risk Assessment

The chemical risk assessment process estimates the likelihood and magnitude of adverse health effects that result from environmental exposure. As defined by the National Research Council's *Risk Assessment in the Federal Government (*NRC, 1983), the key components of EPA's risk assessment process are: hazard identification, dose/response assessment, exposure assessment, and risk characterization. This is shown graphically in Figure 2.

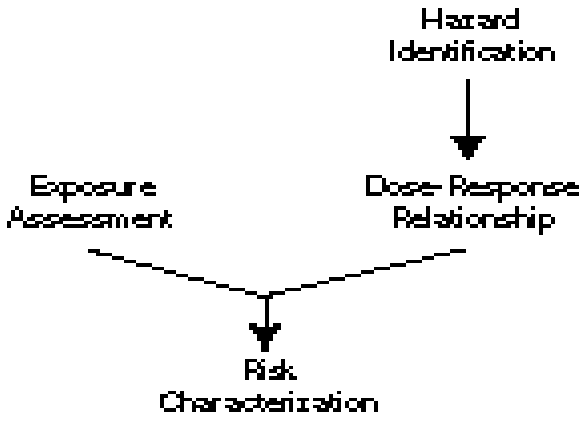


Figure 2. Aspects of Risk Assessment

- ***Hazard identification*** evaluates a contaminant's presence in the environment and its inherent toxicity (i.e., the types and degrees of harmful effects a chemical may cause). Hazard identification involves the review of data for a site to determine what contaminants are present and whether these contaminants are likely to cause harm to humans or other non-human receptors (e.g., fish).

- ***Dose-response assessment*** characterizes the relationship between the magnitude of exposure (i.e., doses) and the occurrence of health effects. Typically, a contaminant's potential for causing adverse health effects is evaluated through a battery of short-term or acute, intermediate or subchronic, and long-term or "chronic" toxicity tests in laboratory animals. These animals are exposed to different doses of a chemical, and the test results are evaluated to determine the relationship between the dose administered/received and the likelihood of adverse effects occuring in the exposed population. A diagram depicting a dose-response relationship is presented in Figure 3.

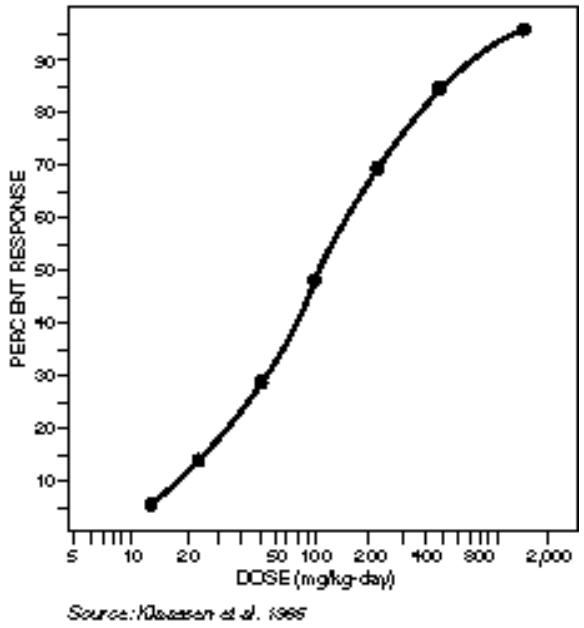


Figure 3. Dose Response Relationship

- ***Exposure assessment*** estimates the level, duration, frequency, and route of exposure(s). The exposure assessment process is further described below.

- ***Risk characterization*** describes the nature and magnitude of the risks by integrating the above factors. By combining estimates of likely or actual exposure with the toxicity of the contaminant, the risks posed by the substance may be characterized. Simply stated,

$$RISK = Toxicity \times Dose \qquad \text{(Eq. 1)}$$

4.2 Risk Assessment Process

In practice, there are five steps involved in conducting a human health or ecological risk assessment. These are: (1) data collection and evaluation, (2) exposure assessment, (3) toxicity evaluation, (4) risk characterization (U.S. EPA, 1989), and (5) uncertainty analysis. Each step, particularly as it relates to human health risk assessment (i.e., the focus of this report), is briefly described in the following sections.

4.2.1 Data Collection and Evaluation

Data collection and evaluation involve gathering and evaluating site data relevant to human health, and identifying those substances present at the site that should be the focus of the risk assessment process (i.e., chemicals of potential concern). Site data may include analytical data for one or more environmental matrices (e.g., soil, groundwater, sediment, surface water, fish tissues, etc.) collected from the area being evaluated, information on the characteristics of the environmental setting that may affect the transport and fate of the contaminants, and information on the sources and releases of the contaminants. Monitoring data need to be collected that are representative of the extent of contamination on the site, as well as that which may have migrated off site, and of sufficient quality and quantity to ensure that the foundation upon which the risk assessment is based is sound. Adequate quality assurance/quality control (QA/QC) procedures must be implemented during both the field and laboratory phases of data collection and evaluation, and data quality objectives (DQOs) should be set to ensure that the samples adequately characterize the degree and extent of contamination (i.e., an adequate number and distribution of samples are taken), and that the analytical limits of detection (LODs) are low enough to detect risks at or below the "acceptable" risk range.

Exposure point concentrations or distributions of concentrations may be estimated for specific pathways, based on the environmental monitoring data and/or predictive chemical modeling techniques. For example, soil residue data may be used directly in assessments pertaining to incidental ingestion of soil, or may be used to model concentrations of chemicals in airborne particulates resulting from activities expected to resuspend the soil. The exposure concentration(s) selected for use in an exposure assessment is dependent upon the exposure descriptor of interest (e.g., average, high-end, or bounding; see below). Typically, conservative estimates of the mean (i.e., 95 percent upper confidence limits of the mean) are used.

4.2.2 Exposure Assessment

Exposure assessment is perhaps the most critical step in achieving a reliable estimate of health risk to humans. Exposure assessment is the process by which: (1) potentially exposed populations are identified; (2) potential pathways of exposure are identified; and (3) chemical intakes/potential doses are quantified. Exposures to chemical contaminants may occur by oral, inhalation, or dermal absorption routes (Figure 4).

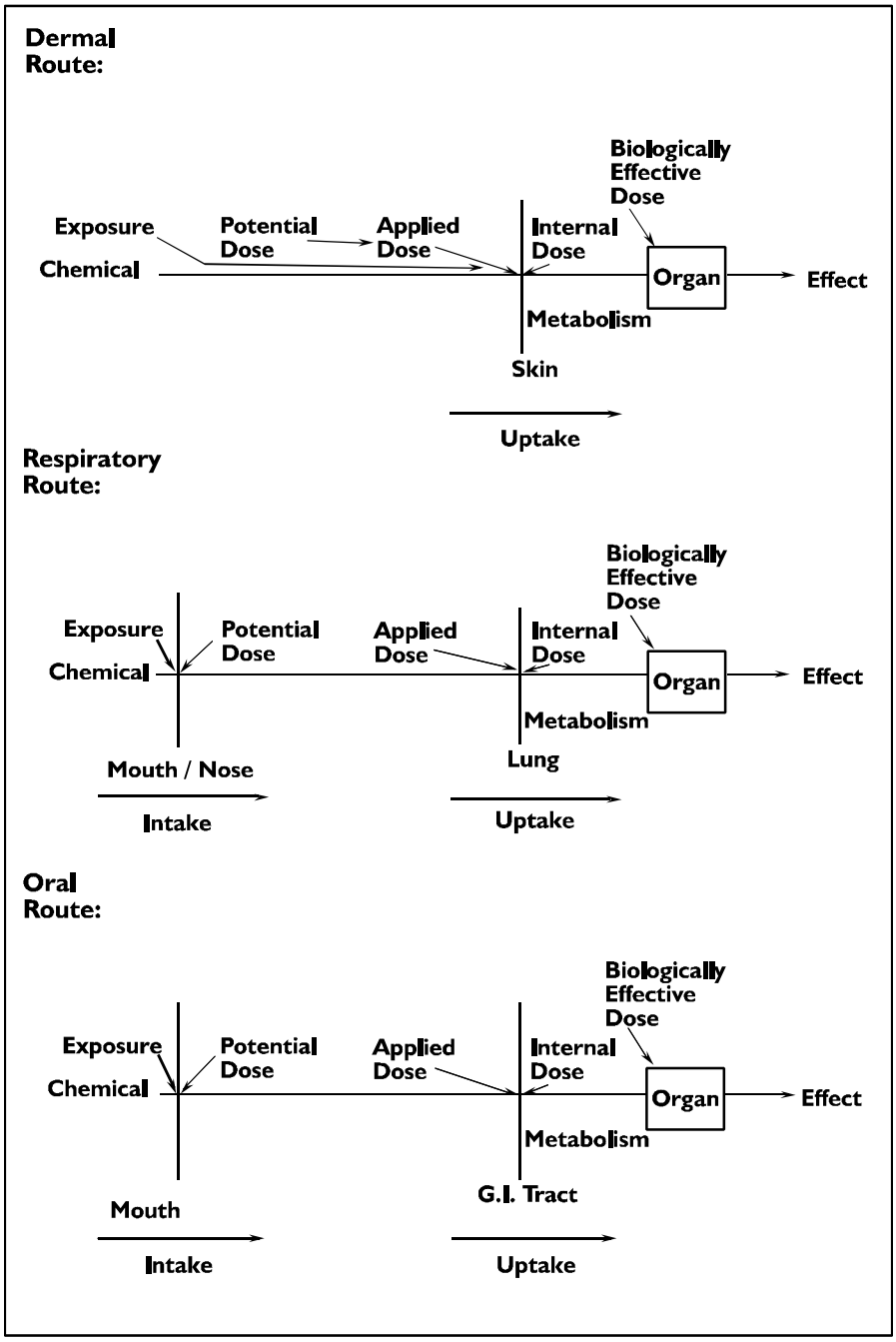


Figure 4. Schematic of Dose and Exposure

Source: U.S. EPA, 1992a

Exposure is commonly defined as contact of visible external physical boundaries (i.e., external boundaries such as the mouth, nostrils, and skin) with a chemical agent (U.S. EPA, 1992a). As described in the *Guidelines for Exposure Assessment*, exposure is dependent upon the intensity, frequency, and duration of contact. The intensity of contact is typically expressed in terms of the concentration of contaminant per unit mass or volume (i.e., µg/g, µg/L, mg/m^3, ppm, etc.) in the media to which humans are exposed (U.S. EPA, 1992a).

Dose refers to the amount of chemical to which individuals are exposed that crosses the external boundary (U.S. EPA, 1992a). Dose is dependent upon contaminant concentration and the rate of intake (i.e., inhalation or ingestion) or uptake (i.e., dermal absorption) and may be normalized to body weight as a function of time (i.e., mg/kg/day). ***Potential dose*** is the amount of chemical which could be ingested, inhaled, or deposited upon the skin without clothing. ***Applied dose*** is the amount of chemical that is actually ingested into the gastrointestinal tract (after food preparation or water treatment), inhaled into the lung (after accounting for the effects of a respirator or particle deposition in the upper airways), or reaches the skin (after penetration through gloves and clothing). Applied dose has sometimes been called ***delivered or deposited dose***. The ***internal dose*** is the amount of chemical absorbed into the body through the gastrointestinal tract, lung or skin. Internal dose has sometimes been called ***absorbed dose***. The toxicologic basis for risk assessment is typically either the applied dose from animal feeding studies or the internal dose from pharmacokinetic studies followed by intraperitoneal or other injected delivery into the test animal. Potential dose may be calculated as follows:

$$DR_{pot} = C \times CR \qquad \text{(Eq. 2)}$$

where:

DR_{pot} = potential dose rate (mg/day);
C = contaminant concentration in the media of interest (mg/cm^2; mg/m^3, mg/g); and
CR = contact rate with that media (cm^2/day; m^3/day; g/day).

The contaminant concentration is the amount of contaminant in the media to which humans are exposed. The contaminant concentration may be affected by dissipation of chemical over time by evaporation, degradation, or other fate processes. Contact rate may be defined as the rate of ingestion, inhalation, or dermal deposition (U.S. EPA, 1997).

Potential doses may also be averaged over body weight and time (mg/kg/day) to calculate an average daily dose. Average daily potential dose rates may be estimated using the standard exposure assessment algorithm shown below (U.S. EPA, 1992a).

$$ADD_{pot} = [C \times CR \times ED \times F] / [BW \times AT] \quad \text{(Eq. 3)}$$

where:

ADD_{pot}	=	potential average daily dose (mg/kg/day);
C	=	contaminant concentration (mg/L, mg/m^3; mg/cm^2);
CR	=	contact rate (L/day; m^3/day; cm^2/day);
ED	=	exposure duration (years);
F	=	frequency of exposure events (days/year);
BW	=	body weight (kg); and
AT	=	averaging time (days).

The contaminant concentration refers to the amount of chemical residue in the media of interest, and contact rate refers to the rate of ingestion, inhalation, or dermal deposition per day. Exposure duration refers to the length of time that contact occurs and is affected by activity patterns; for instance, one year to calculate annual average. Frequency is the number of exposure events over a specified time period. Body weight and averaging time are specific to the population and exposure scenarios being evaluated. The averaging time (AT) is the number of days over which the exposure is averaged. For exposure assessments used to support cancer risk assessments AT is replaced by lifetime (LT) (i.e., 27,375 days = 75 years * 365 days/year). The resulting exposure estimate is referred to as the potential lifetime average daily dose ($LADD_{pot}$). ADD_{pot} and $LADD_{pot}$ are expressed in units of mg/kg/day. Absorbed doses (i.e., ADD_{abs} and $LADD_{abs}$) may be estimated by applying an absorption factor. LADDs/ADDs are also sometimes referred to as chronic daily intakes (CDIs) or subchronic (SDIs), depending on the length over which the exposure occurs. These terms are usually used in Superfund risk assessments (U.S. EPA, 1989).

Average, high-end, and/or bounding estimates may be made using these algorithms. These exposure descriptors account for individual and population variability and represent points on the distribution of exposures (Figure 5).

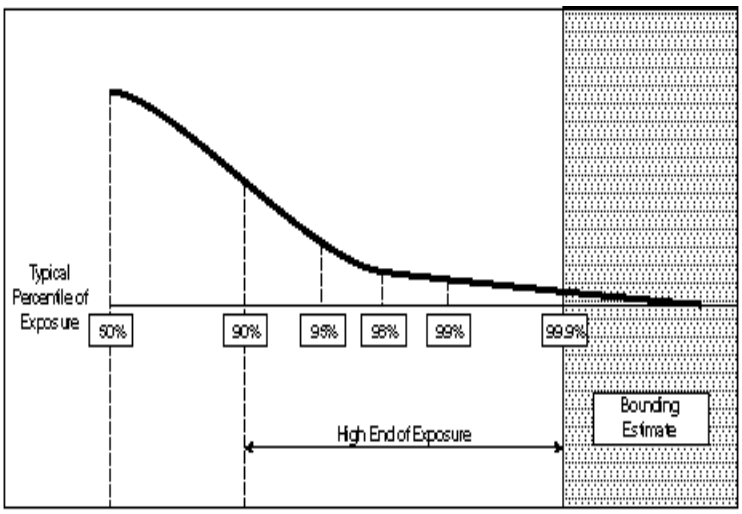


Figure 5. Schematic of Exposure Descriptors

Average dose rates represent the mean and may be estimated using central tendency values for all the parameters in the ADD or LADD. The high-end potential dose rate (90th or 95th percentile) is a reasonable approximation of dose for individuals at the upper end of the distribution of exposures (U.S. EPA, 1992a). High-end values are estimated by setting some, but not all, ADD or LADD parameters to the upper-end values. Finally, bounding potential dose rates are exposures that are estimated to be greater than the highest individual exposure in the population of interest. Bounding estimates are often used in screening-level assessments. In Superfund risk assessments, high-end/bounding estimates are frequently referred to as reasonable maximum exposures (RMEs), and average estimates are referred to as central tendency exposures (CTEs) (U.S. EPA, 1989).

Inputs for the standard exposure/risk calculations described above should be representative of the population/scenarios being evaluated. Contaminant concentration values are generated based on residue and dissipation data collected at the site for the media of interest. Factors such as frequency and duration of use can be derived from actual data on the activities/uses associated with site/scenario-specific uses of a chemical, or from general population survey data on activity patterns and product usage. Other inputs to the exposure calculations such as contact rate (ingestion rate, inhalation rate, skin surface area), body weight, and lifetime may be based on standard exposure factors. Mean and upper-percentile exposure factors based on distributions of data collected from the scientific literature are reported in EPA's *Exposure Factors Handbook* (1997) and EPA's *Risk Assessment Guidance for Superfund* (1989). Table 7 provides a summary of the recommended exposure factors as recently reported by U.S. EPA (1997). Additional information on these factors

is presented in Appendix B. These standard assumptions are suggested for use in PCB risk assessments conducted under the PCB disposal rule.

Factors that may be needed in PCB risk assessments, but that are not provided in the *Exposure Factors Handbook*, include data on the transfer of PCBs from hard surfaces to the human skin; the fraction of PCBs dermally absorbed by the skin; and the flux of PCBs in aqueous media through human skin. For the purposes of risk assessments involving PCBs, a transfer factor of 25 percent should be used. This value represents the transfer fraction observed in a study by Christianson et al. (1986) that evaluated transfer of PCBs from glass and metal surfaces in *in vitro* experiments (i.e., 1-minute contact time with pig and human skin). (See Appendix D.) This is believed to be a conservative value and is appropriate for use in assessments involving dermal contact with surfaces. The absorption fraction recommended for PCB assessments is 14 percent. This is based on *in vivo* studies conducted by Wester et al. (1993) using monkeys (see Appendix D). The recommended K_p value for PCBs (i.e., flux of PCBs in aqueous media through the skin) is 1.3 cm/hr. This is an estimated value for 4-chlorobiphenyl (U.S. EPA, 1992b).

4.2.3 Toxicity Evaluation

A toxicity assessment considers: (1) the types of adverse health effects associated with chemical exposures; (2) the relationships between magnitudes of exposures and potential adverse effects (dose-response relationship); and (3) related uncertainties such as the weight-of-evidence of a particular chemical's carcinogenicity in humans. Toxicity evaluations are generally accomplished in two steps. The first step, hazard identification, is the process of determining whether exposure to an agent can cause an increase in the incidence of an adverse health effect (e.g., cancer, birth defects). Hazard identification also involves characterizing the nature and strength of the evidence of causation. The second step, dose-response evaluation, is the process of quantitatively evaluating the toxicity information and characterizing the relationships between the doses of the chemicals administered or received and the incidence of adverse health effects in the exposed population. From those quantitative dose-response relationships, toxicity values are derived that can be used to estimate the incidence of adverse effects occurring in humans at different exposure levels. Toxic responses are generally classified by EPA as nonthreshold and threshold effects.

Typically, EPA risk assessments rely heavily on existing toxicity values (e.g., Reference Doses for chronic exposure to noncarcinogens [RfDs] and cancer slope factors [SFs]) developed for specific chemicals by EPA to characterize the likelihood of occurrence of nonthreshold and threshold effects in humans, respectively.

4.2.3.1 *Noncarcinogenic Risk (RfDs)*

An RfD for a substance is the daily intake or dose per unit body weight (mg/kg/day) that is likely to be without appreciable risk to human populations, including sensitive subgroups. The RfD allows for the existence of a threshold dose, that is a certain minimum intake of substance below which there will be no observable toxic effects based on the metabolic and detoxifying capacities of the exposed individuals. EPA considers most noncarcinogens to have threshold exposures below which no toxic effects will occur. RfDs are generally calculated by dividing the no-observable adverse effect level (NOAEL) from observations in experimental animals by uncertainty factors (which generally range from 10 to 1,000). These uncertainty factors or safety margins are intended to account for specific types of uncertainty inherent in deriving a single estimate of toxicity from the available data, including variations in the sensitivity of individuals in a population, extrapolation from animals to humans, and other limitations and uncertainties.

EPA has developed RfDs for many chemicals, based on different exposure routes (e.g., oral or inhalation) and different durations of exposure (i.e., chronic, subchronic, or single event). EPA defines a chronic RfD as an estimate of a daily exposure level for the human population that is unlikely to result in deleterious effects during a lifetime. A chronic RfD is used to evaluate the potential noncarcinogenic effects associated with exposure periods longer than 7 years. Subchronic RfDs have been developed by EPA to characterize potential noncarcinogenic effects associated with shorter term exposures (i.e., periods between 2 weeks and 7 years). Therefore, identification of appropriate toxicity values must reflect length of potential exposure. Subchronic RfDs tend to be higher, often by an order-of-magnitude, than chronic RfDs because of assumed shorter exposure duration.

4.2.3.2 *Carcinogenic Risk (SFs)*

For carcinogens, EPA assumes no threshold. This means that there is some finite risk no matter how small the dose. For assessing carcinogens, EPA uses a two-part evaluation in which the substance is first assigned a weight-of-evidence classification and then a slope factor is calculated that defines quantitatively the relationship between dose and response. EPA's weight-of-evidence classification is based on the extent of evidence that chemicals are carcinogenic in humans and experimental animals. The EPA weight-of-evidence classifications are summarized in Table 8.

The slope factor (SF) for a given chemical carcinogen is a plausible upper-bound estimate of the probability of a response per unit intake of that chemical over a lifetime. The slope factor is used

to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.

A number of mathematical models and procedures have been developed to extrapolate from carcinogenic responses observed at high doses in experimental animals to responses expected at low doses in humans. EPA uses the linearized multistage model for low-dose extrapolation. This mathematical model is based on the multistage theory of carcinogenesis where the response is assumed to be linear at low doses. EPA further calculates the upper 95th percent confidence limit of the slope of the resulting dose-response curve. This value is known as the slope factor (SF). The SF, as developed by EPA, converts the average daily intake of chemical over a lifetime directly to a cancer risk. The SF is expressed in units of $(mg/kg/day)^{-1}$.

4.2.3.3 *Sources of Toxicity Data*

The RfD (oral and inhalation, subchronic, chronic) and SF (oral and inhalation) values used in many EPA risk assessments are obtained from the following sources:

- EPA's Integrated Risk Information System (IRIS),
- Health Effects Assessment Summary Tables (HEAST), and
- EPA-NCEA Regional Support Provisional Values.

All available RfDs and SFs from the above sources are based on oral and inhalation routes of exposure; no RfDs and SFs are available for the dermal route of exposure. U.S. EPA (1989, 1992a) recommends that the oral RfDs and SFs be used to assess the risk of dermally absorbed chemicals. U.S. EPA (1992a) acknowledges the considerable uncertainty introduced into a risk assessment by this approach. First, the risk associated with point-of-entry (skin) effects for locally acting toxic agents cannot be estimated from oral toxicity data. Second, unlike orally administered compounds, dermally absorbed chemicals are not subjected to first-pass hepatic metabolism before reaching the systemic circulation. Finally, oral dose response relationships are based on administered dose, whereas dermal dose estimates are absorbed doses. Therefore, using oral slope factors and RfDs to extrapolate risks and hazards from dermal exposure is a non-conservative approach.

4.2.3.4 *Toxicity Data for PCBs*

The carcinogenic weight-of-evidence classification for PCBs is B2, probable human carcinogen (U.S. EPA, 1998). The SF for PCBs used in the Spill Cleanup Policy was 4.0 $(mg/kg/day)^{-1}$ for both oral and inhalation exposures (U.S. EPA, 1987b). Subsequently, EPA posted

a SF of 7.7 $(mg/kg/day)^{-1}$ in EPA's Integrated Risk Information System (IRIS). More recently, EPA/ORD (U.S. EPA, 1996) conducted another cancer dose-response assessment for PCBs and proposed a new set of cancer slope factors that focuses on PCB mixtures (see Appendix C). The ORD assessment uses a tiered approach, as shown in Table 9.

When developing a risk-based cleanup application under 40 CFR 761.61(c), both the cancer and non-cancer endpoints must be addressed for each of the commercial PCB mixtures or the specific congeners at that site. Alternatively, a total toxicity factor of 4.0 $(mg/kg/day)^{-1}$ may be used to calculate the risk from both cancer and non-cancer endpoints. For determining the risk from cancer, the cancer slope factors in the EPA/ORD guidance (U.S. EPA, 1996) may be used. If an applicant chooses not to use the total toxicity factor of 4.0 $(mg/kg\text{-}day)^{-1}$ for estimating the risk from both cancer and non-cancer endpoints, they must, at a minimum, account for the risk from non-cancer endpoints for neurotoxicity, reproductive and developmental toxicity, immune system suppression, liver damage, skin irritation, and endocrine disruption for each of the commercial mixtures found at the cleanup site. For some commercial mixtures of PCBs and some end-points, the RFDs found in IRIS may be used. The oral RfDs for PCBs are 0.02 μg/kg/day for Aroclor 1254 and 0.07 μg/kg/day for Aroclor 1016 (U.S. EPA, 1998a).

For dermal exposure scenarios, the oral slope factor and RfDs should be used. However, a dermal absorption factor must be used to convert potential dermal doses to absorbed doses. This is necessary because the oral toxicity values are based on internal doses. For the purposes of calculating the absorbed dose, it should be assumed that 14 percent of the dose of PCBs applied to the skin are dermally absorbed. This dermal absorption fraction reflects the PCB absorption factors reported in Wester et al. (1993) for Aroclors 1242 and 1254 for *in vivo* studies using monkeys (see Appendix D). The K_p value (flux of PCBs in aqueous media through the skin) is 1.3 cm/hr, based on 4-chlorobiphenyl (U.S. EPA, 1992b). A related factor for dermal assessments is transfer of PCBs from hard surfaces to the skin. For the purposes of PCB risk assessments, a transfer factor of 25 percent should be used. This value represents the transfer fraction observed in a study by Christianson et al. (1986) that evaluated transfer of PCBs from glass and metal surfaces in *in vitro* experiments (i.e., 1-minute contact time with pig and human skin).

4.2.3.5 *Standard EPA Risk Assessment Guidance*

EPA has developed several standard EPA guidance documents that should be consulted for more detailed information of the conduct of risk assessments. Some of the documents are listed below:

- Risk Assessment Guidance for Superfund, Volume 1 - Human Health Evaluation Manual (see Appendix E for excerpts).
  - Part A - Human Health Evaluation Manual (U.S. EPA, 1989)
  - Part B - Development of Risk-Based Preliminary Remediation Goals (U.S. EPA, 1991a)
  - Part C - Risk Evaluation of Remedial Alternatives (U.S. EPA, 1991b)
  - Part D - Standardized Planning, Reporting, and Review of Superfund Risk Assessments (1998b)
- Exposure Factors Handbook (U.S. EPA, 1997) (see Appendix B for excerpts)
- Guidelines for Exposure Assessment (U.S. EPA, 1992a) (see Appendix E)
- Dermal Exposure Assessment: Principles and Applications (U.S. EPA, 1992b)
- Soil Screening Guidance: Technical Background Document (U.S. EPA, 1995b)
- National Oil and Hazardous Substances Pollution Contingency Plan (U.S. EPA, 1990)

4.2.4 Risk Characterization and Interpretation of RA Results

Risk characterization summarizes and combines outputs of the exposure and toxicity assessments to characterize baseline risks, both in quantitative expressions and qualitative statements. During risk characterization, exposure estimates are compared to chemical-specific toxicity information to determine whether current or future exposures at or near the site may be of potential concern.

Risk characterization integrates toxicity and exposure data to provide quantitative estimates of carcinogenic risk and systemic hazards. Carcinogenic risks represent the incremental probability that an individual will develop cancer over a lifetime as a result of exposure to a chemical compound. EPA usually assumes a non-threshold dose-response for carcinogens (i.e., some finite risk no matter how small the dose). For contaminants with carcinogenic endpoints, individual lifetime risk is estimated by multiplying the $LADD_{pot}$ by the cancer potency slope factor as follows:

$$R_i = LADD_{pot} \times SF \qquad \text{(Eq. 4)}$$

where:

R_i = excess individual lifetime cancer risk level (unitless);
$LADD_{pot}$ = lifetime average potential daily dose (mg/kg/day); and
SF = cancer potency slope factor $(mg/kg/day)^{-1}$ (also known as Q_1*).

R_i represents the probability of excess cancer cases over a lifetime. For example, a risk level of 10^{-6} indicates that an excess cancer case is projected to occur in no more than 1 out of a million individuals exposed to this LADD over a lifetime. Annual excess cancer risks may be estimated by dividing the lifetime risk value by the average lifetime (70 years). LADDs are calculated as described previously. Slope factors are conservative estimates of the incremental probability of cancer from a unit dose of chemical over a lifetime. They are chemical-specific values derived from animal toxicity studies and/or human epidemiological data and represent the upper 95 percent confidence interval. As specified in U.S. EPA's National Oil and Hazardous Substances Pollution Contingency Plan; Final Rule (U.S. EPA, 1990), a risk range of 10^{-4} to 10^{-6} is generally considered to be acceptable. However, the selection of an appropriate level of risk is often based on site- and population-specific factors.

Population risks represent conservative estimates of the number of individuals in an exposed population that are likely to be affected by PCB exposure. Population risks are calculated as follows.

$$POP_{risk} = R_i \times POP_{exposed} \qquad \text{(Eq. 5)}$$

where:

POP_{risk} = population risks (number of individuals in an exposed population that are projected to be affected);
R_i = excess individual lifetime cancer risk level (unitless); and
$POP_{exposed}$ = population exposed (number of exposed individuals in the population).

Table 10 shows the relationship between individual lifetime cancer risk values and the annual cancer risks for a population of 250 million people.

For chemicals with noncancer endpoints (i.e., systemic effects) where a threshold dose-response relationship is assumed, hazard quotients are calculated to characterize the risks associated with exposure. Hazard quotients are unitless values that are calculated by dividing the average daily dose by a value that represents a toxicity endpoint and are calculated as follows.

$$H = ADD / RfD \quad \text{(Eq. 6)}$$

where:

H = hazard quotient (unitless);
ADD = average daily dose (mg/kg/day); and
RfD = reference dose or other datum indicative of the toxicity endpoint of interest (mg/kg/day).

If the hazard quotient is greater than one, an effect would be expected; but if the ratio is less than one, no effects would be expected. Typically, the reference doses used in these calculations are values below which no adverse health risks would be expected. They are derived by dividing NOAELs by uncertainty and safety factors. RfDs have been developed by EPA for numerous chemical substances based on available animal toxicity data and human epidemiological data. Hazard quotients are not probabilistic statements of risk.

4.2.5 Uncertainty Analysis

Risk characterization provides decision makers with a qualitative evaluation of the accuracy of the risk estimates. In characterizing risks from exposure to chemical substances, the variability and uncertainty associated with the exposure/risk estimates should be addressed. The risk characterization should provide information on: (1) potential measurement errors based on the precision and accuracy of the available data, (2) variability of the input data used in the exposure/risk estimates, and (3) uncertainty that results from data gaps or the assumptions used. The risk characterization also assesses the relative importance of these components on the estimates of exposure/dose and risk.

Uncertainty may be introduced into the exposure/risk calculations at various stages of the risk assessment process. Uncertainty may occur as a result of: (1) the techniques used to sample and analyze chemical residues, (2) chemical fate and transport factors, (3) the selection of exposure scenarios and exposure factors, (4) the uncertainties associated with toxicity data that have been extrapolated from high doses in animals to low doses in humans, and that do not account for the interactions of exposures to multiple chemical substances over a lifetime, and (5) the potential size of the exposed populations and subpopulations. Variability can occur as a result of variations in individual day-to-day or event-to-event exposure factors or variations among the exposed population. Variability can be addressed by estimating exposure for the various descriptors of exposure [i.e.,

central tendency (mean or median), high-end (90th or 95th percentile), or bounding (100th percentile)] to represent points on the distribution of exposures.

4.3 Types of Risk Assessments and Related Analyses

Risk assessments can take on many forms. The type and style is dependent on the goals of the assessment. For example, a tiered approach to risk assessment is sometimes implemented in which sites are first screened using the most conservative data and assumptions to determine the upper range risk levels. Exposure/risk estimates can be determined based on single exposure/risk descriptors (i.e., point estimate), or on a probability density function. Risk assessments can also be constructed to represent baseline conditions (i.e., existing conditions, before any form of remediation), or the conditions that are anticipated based on one or more remedial alternatives. Several of the concepts are described briefly in the following sections.

4.3.1 Screening-Level Approaches

The screening-level approach uses the most conservative data and assumptions to determine upper range risk levels. Screening level assessments allow for low-risk sites to be eliminated from further evaluation at an early stage of the investigation if the estimated upper range risks are in the "acceptable" range. Another type of screening approach utilizes pre-determined risk-based concentrations (RBCs) or preliminary remediation goals (PRGs) (U.S. EPA, 1991a). RBCs and PRGs are chemical- and media-specific concentrations below which risks are not expected to be significant. These concentrations are calculated by reversing the risk assessment algorithms and assuming a target risk value (e.g., 10^{-6} for carcinogens) to calculate a chemical concentration of low concern in the media of interest. Several EPA Regions have developed RBCs for various population groups (e.g., residential, commercial/industrial workers) and media (e.g., soil, drinking water). These are sometimes used as screening tools to determine whether contaminant concentrations observed at a site are likely to result in risks to human health. EPA has also developed methods for calculating risk-based screening concentrations for soil. (See *Soil Screening Guidance: Technical Background Document*, U.S. EPA, 1995b.)

4.3.2 Tiered Approaches

If necessary, screening-level assessments can be refined, in one or more phases (i.e., using upper-tier assessments), to provide more "realistic" estimates of exposure. For example, if significant risks are estimated in a screening level assessment, site-specific exposure assumptions are sometimes used to replace the most conservative assumptions used in the screening approach. Central tendency

risks may be used in conjunction with reasonable maximum risks to bracket the anticipated risks at the site. In general, the output (i.e., expression of exposure/risk) of a screening-level exposure/risk assessment, and some upper-tier assessments are single values to which a risk descriptor is assigned (e.g., central tendency, high-end, bounding, reasonable maximum exposure, etc.). Another type of upper-tier approach uses a probabilistic method to estimate exposure/risks at a site.

4.3.3 Deterministic Methods Techniques

Exposure/risk estimates can be determined based on single exposure/risk descriptors (i.e., point estimate), or on a probability density function. Deterministic techniques typically calculate a single value that represents exposure/risk within a specific range of the distribution of exposure/risk. As discussed previously (see Figure 5), average exposure/risks represent the mean and may be estimated using central tendency values for all the parameters in the exposure/risk algorithms. The high-end exposure/risk level (90th or 95th percentile) is a reasonable approximation of dose for individuals at the upper end of the distribution of exposure/risks (U.S. EPA, 1992a). High-end values are estimated by setting some, but not all exposure/risk parameters to the upper-end values. Finally, bounding exposure/risks levels are those estimated to be greater than the highest individual exposure in the population of interest. Bounding estimates are often used in screening-level assessments. In Superfund risk assessments, high-end/bounding estimates are frequently referred to as reasonable maximum exposures (RMEs), and average estimates are referred to as central tendency exposures (CTEs).

4.3.4 Probabilistic Approaches

In contrast to deterministic methods, probabilistic assessments estimate the distribution of exposures/risks, and estimate the probability that an individual in the population could experience various exposure/risk levels. For example, for an exposure/risk estimate at the 95th percentile of the distribution, there is a 95 percent probability that individuals in the population will be below that value. Probabilistic assessments also provide a measure of variability associated with an estimate of the central value. Thus, for a given estimated exposure distribution, the mean and variance are calculated. These estimates of the range and distribution of exposure/risk are developed through a statistical technique called Monte Carlo analysis. The Monte Carlo technique uses the full distribution of pertinent data, instead of single-point estimates, to characterize the input variables. There are two advantages to this approach. First, the use of conservative single point estimates for numerous variables may lead to a systematic overestimate of exposure. Monte Carlo simulations avoid the problem of overestimation by using input distributions. Second, the use of single point estimates to predict exposure does not provide any information on the variability of the estimated exposure.

Monte Carlo simulations generate variance estimates. Thus, Monte Carlo analysis addresses the issues of how specific exposures are likely to vary among the population. Variability is expressed as the confidence (expressed as a probability) that individuals in the population are below specified values. In Monte Carlo analysis, input variables are characterized by a probability density function (pdf). The stochastic sampling experiment involves the generation of random numbers which are used to sample these input probability distributions. The sampled values are then used in the specified equation, which calculates exposure. The equation is recalculated numerous times and the results are presented as a cumulative probability distribution. One type of software used to perform Monte Carlo simulations is "@Risk" by Palisade, Inc., which runs in conjunction with Microsoft's Excel®. "Crystal Ball" is another product that allows for the performance of Monte Carlo techniques.

There are two key assumptions of a Monte Carlo simulation. First, there must be sufficient data on the input variables to accurately characterize the input distribution. The shape of input distributions can be evaluated using fit tests which are part of standard statistical packages. Second, input variables are independent (or that correlations are characterized and taken into account). Correlated variables have the greatest impact on the tails of the distribution, which may be the critical region if the 95th percentile is of interest. An example of two correlated variables is body weight and surface area of the skin. These variables can be used in a Monte Carlo analysis by using a single composite variable which has been developed based on the distributions of body weight and skin surface area.

4.3.5 Baseline vs. Remedial Options Evaluations

Risk assessments can be constructed to represent baseline conditions (i.e., existing conditions, before any form of remediation) (U.S. EPA, 1989), or the conditions that are anticipated based on one or more remedial alternatives (U.S. EPA, 1991b). Baseline risk assessments typically use measured concentrations in media collected at the site, or concentrations modeled from site data (e.g., measured concentrations of contaminants in soil may be used to model concentrations in airborne dust from soil disturbances). Evaluations based on remedial options typically use calculated or modeled exposure point concentrations that are anticipated based on remedial actions. For guidance on conducting risk assessments for remedial alternatives, refer to *Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual, Part C - Risk Evaluation of Remedial Alternatives* (U.S. EPA, 1991b).

Risk assessments conducted in response to the TSCA PCB disposal rule are likely to provide estimates only for conditions related to the proposed disposal method. Thus, baseline or remedial options assessments may not be relevant to risk assessments conducted under this rule.

5.0 GUIDANCE FOR THE REVIEW OF PCB RISK ASSESSMENT DOCUMENTS

The purpose of this section is to provide risk assessment reviewers with some general guidance for critically evaluating the results of a PCB risk assessment. A risk assessment review template is provided at the end of this section to assist reviewers in completing reviews in a standardized manner. The information provided in the template will eventually be input into a PCB risk assessment database which is currently under development.

Reviewers of risk assessment documents should be cognizant of the many aspects of the study design, implementation, and presentation that can affect the quality of the product and the interpretation of results. These factors range from sampling and data analysis to development of the site conceptual model and selection of exposure factors and toxicity information. A thorough review of each of these risk assessment components is essential to ensure that PCB risks are adequately characterized and appropriate risk management decisions can be made.

5.1 Adequacy of the General Site Information

An essential component of any risk assessment is that the objectives and scope of the assessment be clearly stated. For example, does the assessment address baseline or remedial alternative risks; is it intended as a screening level or upper tier approach; and does it evaluate central tendency or upper percentile risks? In addition, site conditions must be described in adequate detail. The following should be included to assist the reviewer in evaluating whether the risk assessment is representative of the site condition:

- A site map that includes details on the topography and source areas
- A complete history of the site, including land use patterns and PCB uses on site
- An overview of the nature of contamination.

Prior to data collection and evaluation, the risk assessor typically reviews existing site information such as historic records, topographic maps, and media-specific data to develop a site conceptual model that will define the scope of the risk assessment. The site conceptual model (Figure 6) summarizes the exposure pathways and populations to be evaluated, and forms the basis of the data collection effort. The risk assessment document must provide the rationale for the site conceptual model used.

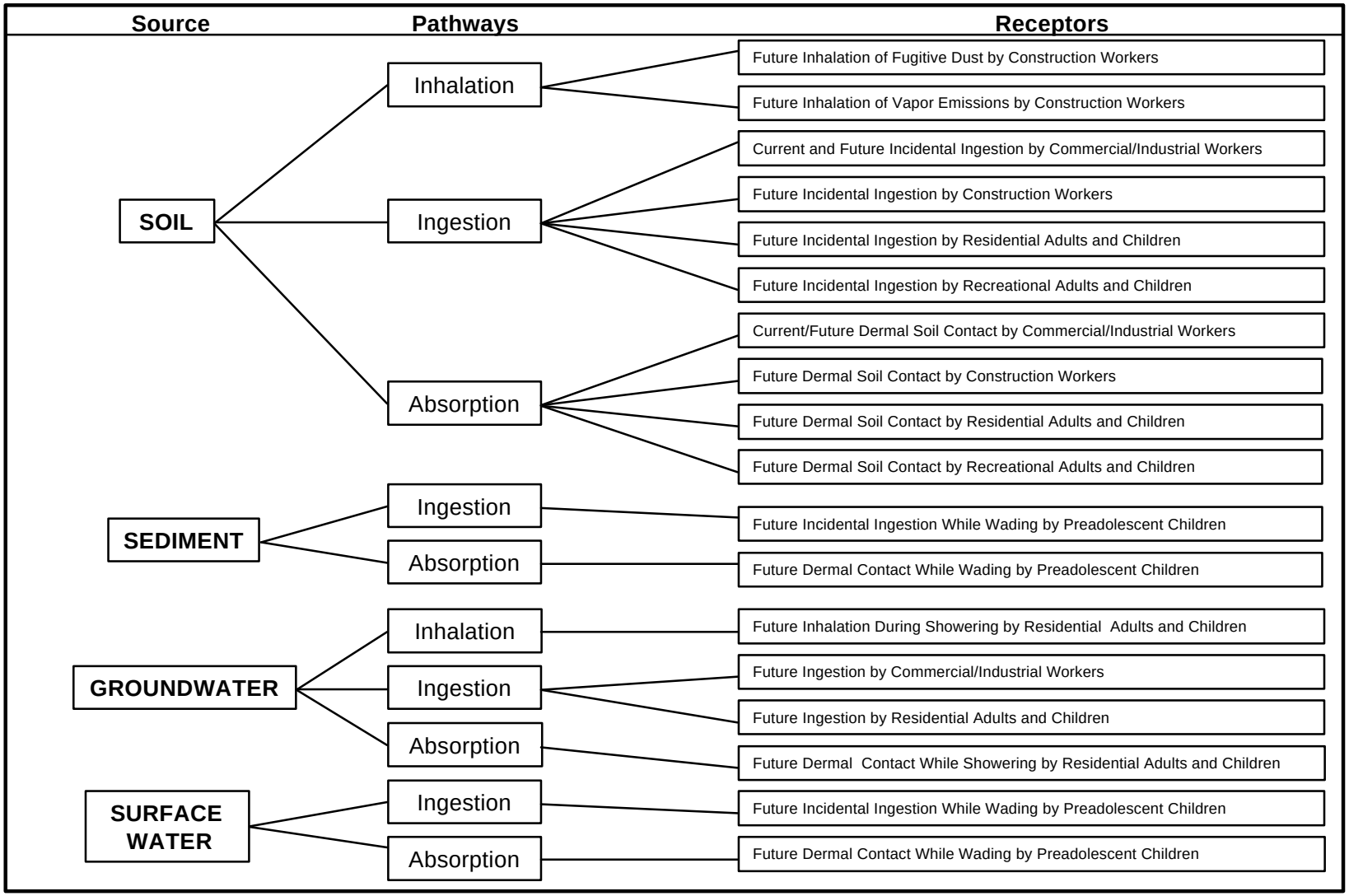


Figure 6. Example of a Site Conceptual Model

5.2 Adequacy of Data

As discussed previously, a key component of the risk assessment process is data collection and evaluation. The overall objective of this step is to produce data that can be used to assess risks to human health with a known degree of certainty. Thus, the data must be adequate in terms of completeness and representativeness. An overview of the data quality objectives developed for the site and a description of the data collected should be included in the risk assessment. Justification as to the data's appropriateness for meeting the objectives of the assessment must also be provided. The following are some data collection and evaluation issues that need to be considered in assessing the adequacy of the data used to assess health risks.

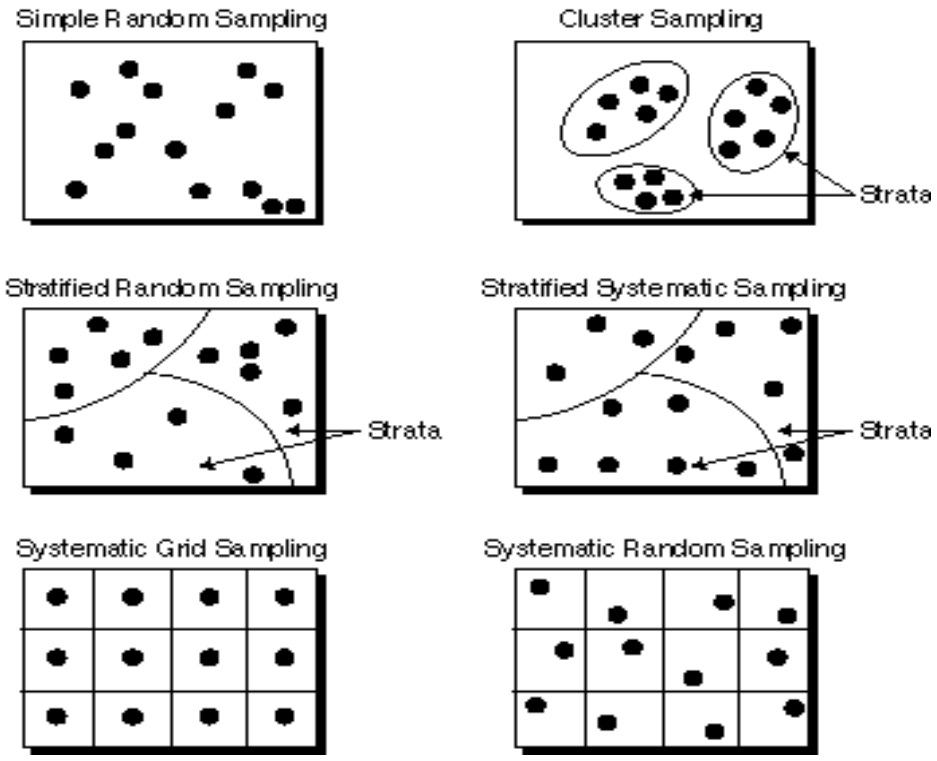
5.2.1 Media of Concern

The media of concern at a site could include soil, subsurface soil, sediment, surface water, groundwater, air, leachate or debris, liquid or solid waste, plant or animal tissue, and/or other media. The reviewer needs to ensure that the risk assessment document provides adequate information to determine whether the media were properly selected (i.e., a narrative description of the site, and/or site maps that depict the terrain, as described previously). Based on the description of the site, it should be determined whether all relevant media were evaluated, and whether the rationale for selecting (or not selecting) certain media was appropriate. For example, selecting subsurface soil and not surface soil for incidental residential soil ingestion scenarios at an undisturbed site may not be appropriate. However, subsurface soil levels may be relevant for construction worker scenarios at the same site.

5.2.2 Sample Collection Methods

One of various approaches may be used to conduct sampling, but the overall goal is to ensure that the site is properly characterized. This means that representative PCB concentrations may be estimated for the media of interest, that trends in PCB contamination can be distinguished, and that hot spots can be identified. Some common sampling methods are presented in Figure 7 (U.S., EPA, 1992c). Selection of one of these methods is frequently based on the objectives of the risk assessment. For example, a stratified random sampling design may be appropriate for collecting representative soil samples, but may not be appropriate for examining the extent of a plume of groundwater contamination. The sampling method should be described in the risk assessment, along with the rationale for its selection. In addition, any sampling problems that could affect the analytical results should be described. For example, potential contaminant losses from sampling, preservation, or storage may result in an underestimate of risk. In contrast, the introduction of extraneous

contamination may result in an overestimate of risk. However, the former is of greatest concern for the protection of human health.



Source: U.S. EPA (1992c)

Figure 7. Common Sampling Designs

5.2.3 Sample Size

An important consideration is whether the sample size and distribution is sufficient to adequately characterize the spatial extent and variability of contamination at the site. The sample size required to adequately characterize a site is based on factors such as the relative size of the site (i.e., larger sites require more samples; hot spots may be missed if sampling is sparse at a large site); diversity of the site (i.e., if there are areas that are physically different from one another on the site) the variability of PCB concentrations at the site (i.e., more samples are needed if a wide range of concentrations are observed to ensure that the estimated exposure point concentration accurately reflects conditions at the site); and the desired level of confidence in the estimated exposure point concentrations (e.g., the larger the sample set, the greater the confidence that an estimated mean value is representative of the average concentration at the site). For more information on determining the appropriate sample size at a site, refer to U.S. EPA (1992c) and Gilbert (1987).

5.2.4 Detection Limits

The detection limits for the media of interest must be low enough to detect a risk at a target risk level (e.g., 1 x 10^{-6}). Inappropriate detection limits may, in effect, result in an underestimation of risk. The target risk level may be used to back-calculate the required limit of detection by rearranging the risk assessment algorithm. For example, assuming an inhalation rate of 13 m^3/day and a residence time of 6 years, the limit of detection necessary to calculate inhalation risks at a level at or below a target risk level of 1 x 10^{-6} for analysis of indoor air could be calculated as follows:

$$RISK_{inhalation} = \frac{C * IR * FR * ED * SF}{BW * LT * 365\ days/year} \quad \text{(Eq. 7)}$$

where:

$RISK_{inhalation}$	=	inhalation risk (unitless);
C	=	concentration of PCBs in air (mg/m^3);
IR	=	inhalation rate (m^3/day);
FR	=	frequency of exposure (days/year);
ED	=	duration of exposure (years);
SF	=	slope factor (mg/kg/day^{-1});
BW	=	body weight (kg); and
LT	=	lifetime (years).

Rearranging to calculate concentration gives:

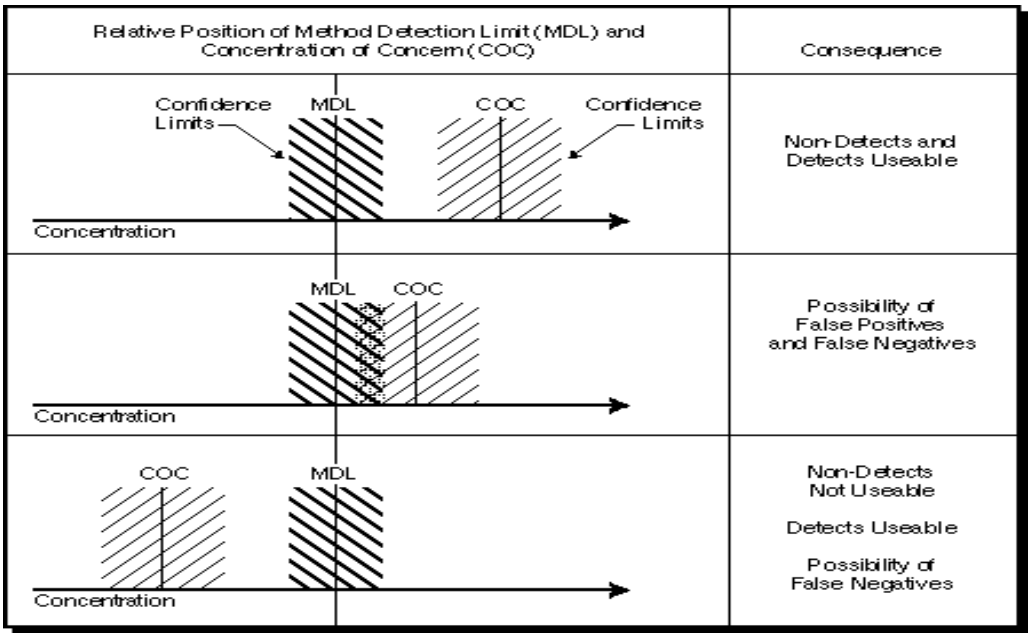
$$C = \frac{Risk_{inhalation} * BW * LT * 365\ days/year}{IR * FR * ED * SF} \quad \text{(Eq. 8)}$$

Finally, substituting the target risk level and exposure assumptions gives:

$$C = \frac{10^{-6} * 71.8\ kg * 75\ years * 365\ days/year}{13\ m^3 * 350\ days/year * 6\ years * 4\ mg/kg/day^{-1}} \quad \text{(Eq. 9)}$$

$$C = 0.018\ ug/m^3 \quad \text{(Eq. 10)}$$

Published risk-based concentrations (RBCs), such as those developed by EPA Region 3 or site-specific preliminary remediation goals, as discussed in Section 4.3.1 are sometimes used to select appropriate detection limits for the media/scenarios of interest. Figure 8 graphically presents the importance of detection limits in assessing risk. For the purposes of calculating the exposure point concentration for use in PCB risk assessments, one-half the sample detection limit should be used as a proxy concentration. This procedure is recommended to account for the possibility that PCBs may be present in a sample at levels below the detection limit.



Source: U.S. EPA (1992c)

Figure 8. Relative Importance of Detection Limits in Risk Assessment

5.2.5 Analytical QA/QC

The analytical method used to determine the PCB concentrations in the samples must be appropriate for the media of interest. Table 11 presents a summary of test methods for PCBs. The risk assessment report should indicate the test method used and the rationale for its selection. PCBs can be analyzed as total PCBs, Aroclors, or PCB congeners. If Aroclors are analyzed individually, the results should be summed to calculate total carcinogenic risks from PCBs. Likewise, congener-specific data should be combined for estimating total PCB risk, except in cases where risks of dioxin-like congeners are being evaluated. For dioxin-like PCBs, the TEF approach should be used to

calculate the toxicity equivalent (TEQ) concentration. The type of analysis and method for assessing total PCBs or dioxin-like PCBs should be clearly outlined in the risk assessment report.

Equally important to the selection of an appropriate test method is adequate quality assurance/quality control (QA/QC) measures. Measurement error can occur from sample collection variation, as discussed above, or from analytical or data processing variations. QA/QC procedures are intended to correct for these variations. Accuracy (i.e., the measure of the closeness of a reported concentration to its actual concentration) can be determined by analyzing samples that have been spiked with a known amount of PCBs. Losses in site samples, can be corrected using the percent recovery from the spikes, if necessary. Field, trip, and method blanks may be used to identify biases related to contamination during sample collection, shipment, and analysis, respectively. Precision (i.e., the quantitative measure of variability) can be measured by analyzing duplicate field samples and/or analytical standards. At a minimum, one field duplicate for each environmental medium should be collected for every 20 site samples (U.S. EPA, 1992c). If less than 20 site samples are collected, one field duplicate should suffice. Analytical data that do not meet the specific data quality criteria, are undetected, or are estimated, require remark codes or qualifiers (flags). Some common data qualifiers are presented in Table 12 along with an indication of their acceptability for use in risk assessment (U.S. EPA, 1989). Typically, the analytical data used in risk assessment are validated by an independent reviewer before being used in the assessment. This is intended to ensure that the data have been reported correctly, and that data flags have been included, as needed. The risk assessment report should address any data quality issues that could potentially affect the interpretation of risks.

5.3 Appropriateness of Methods for Selecting Exposure Concentrations

Media-specific exposure point concentrations are calculated from the analytical data from the site, and used to estimate exposure/risk. The 95 percent upper confidence limit (UCL) of the arithmetic mean is typically used to estimate reasonable maximum exposures. This value is a conservative estimate of the average concentration found at the site. The 95 percent UCL of the arithmetic mean is derived using the following formula:

$$95\%\ \text{UCL} = \overline{X} + t_{\substack{\alpha = 0.05 \\ df = n - 1}} \times \frac{\text{st dev}}{\sqrt{n}}$$

where:

95% UCL = 95% upper confidence limit of the arithmetic mean;
X = arithmetic mean value of composite samples;

t = t-value (one-tailed);
α = probability of a larger value than the upper confidence level;
df = degrees of freedom (n-1)
st dev = standard deviation; and,
n = number of composite samples.

It should be noted that use of this calculation with raw data from the site assumes that the data are normally distributed; for lognormally-distributed data, logtransformed data are typically used to calculate the 95 percent UCL. In cases in which the 95 percent UCL exceeds the maximum concentration detected at a site, the maximum detected value is typically used to estimate a reasonable maximum exposure to that chemical. The use of maximum concentrations may also be more appropriate in cases where the samle size is small or when the data are distributed neither normally nor lognormally. In some instances (i.e., for estimating central tendency exposures), use of a mean value may be appropriate. However, for the purposes of conducting screening-level, or second tier, conservative assessments, the 95 percent UCL is recommended.

As discussed above, for samples in which PCBs are not detected, one-half the sample detection limit should be used in calculating the exposure point concentration. Also, duplicate samples should be averaged arithmetically. This average, representing one sample, is composited with all other samples collected in the same sampling location for the purposes of calculating the exposure point concentration. Further, multiple samples from a single sampling location should be composited (i.e., averaged) before incorporating the values into the exposure point concentration calculation. The purpose of this method is that averaging duplicate samples, and compositing samples from the same location, reduces any biases that might be introduced by considering the samples separately.

The risk assessment reviewer should ensure that the data used in calculating the exposure point concentration are handled correctly, and the results of the calculations are correct. If desired, the standard reporting tables provided in U.S. EPA (1998b) can be used by the reviewer to organize the data inputs used in the risk assessment, for the purposes of checking the accuracy of the calculations.

5.4 Reasonableness of Potentially Exposed Populations Identified

Next, the reviewer should ensure that all relevant potentially exposed populations have been evaluated in the risk assessment. Exposed populations could include commercial/industrial workers, residents, construction workers, other occupational groups such as indoor laborers, or trespassers,

recreational groups, or site visitors. Typically, the selection of potentially exposed populations is dependent upon the current and future anticipated land use at the site. For example, a site that is currently used for commercial/industrial purposes may eventually be used for residences. If this is the case, a risk assessment that addresses only commercial/industrial populations would not be appropriate because it could underestimate risks for future residents who would be expected to have higher exposures for most scenarios (e.g., because exposure frequency and duration would almost always be greater).

Another consideration in evaluating the selection of populations for the risk assessment is whether highly exposed or sensitive populations were evaluated. Highly exposed populations could include sports or subsistence fishermen and their families, breast-fed infants, or occupational groups that would be expected to have increased levels of exposure as a result of job related activities. Sensitive populations could include children or infants that are known to have higher contact rates than adults (e.g., soil ingestion among infants and children under 6 years of age), or those with increased susceptibility to the effects of PCB exposure. The risk assessment should provide adequate justification for the selection of the populations of concern. In general, the reviewer should ensure that all relevant populations are evaluated, and most importantly, that the most highly exposed population is included.

5.5 Appropriateness of Exposure Scenarios Selected

The site conceptual model forms the basis of the scenarios evaluated in the risk assessment (See Figure 6). Exposure scenarios are a function of the potentially exposed population, the possible routes of exposure (i.e., ingestion, inhalation, or dermal absorption) for the various types of contaminated media at the site, and the pathway by which the contaminated media reaches the human receptor. Examples of some key exposure pathways according to exposure route and media are presented in Table 13.

The scenarios selected must be representative of the potential for exposure among site populations, and provide a conservative estimate of risks at the site. The risk assessment reviewer must ensure that all relevant exposure pathways are considered and that pathways that are eliminated from consideration are properly justified. For example, groundwater pathways may not be considered if groundwater is not the current source of drinking water on site. However, if the potential exists for future groundwater use, the scenario should be evaluated for future populations.

5.6 Appropriateness of Exposure Algorithms and Assumptions

The algorithms used to calculate exposure must be appropriate for the media/population/ exposure scenario of interest and assumptions used must be reflective of the exposure conditions. These algorithms should be clearly presented in the risk assessment document submitted to EPA. The risk assessment reviewer is responsible for ensuring the algorithms used are mathematically correct and that they are appropriate in terms of their relevance to the exposure scenario. Examples of some common exposure algorithms are presented below according to the exposure route. Standard exposure assumptions were presented previously in Table 7 and Appendix B.

Ingestion

Incidental Soil (or Sediment) Ingestion

$$LADD = [C_{soil} * IngR_{soil} * EF * ED] \setminus [BW * LT]$$

where:

C_{soil}	=	Contaminant concentration in soil or sediment (mg/g);
$IngR_{soil}$	=	Soil or sediment ingestion rate (g/day);
EF	=	Exposure frequency (days/year);
ED	=	Exposure duration (years);
BW	=	Body weight (kg); and
LT	=	Lifetime (75 years * 365 days/year = 27,375 days).

Ingestion of Drinking Water

$$LADD = [C_{water} * IngR_{drinking\ water} * EF * ED] \setminus [BW * LT]$$

where:

C_{water}	=	Contaminant concentration in water (mg/L);
$IngR_{drinking\ water}$	=	Drinking water ingestion rate (L/day);
EF	=	Exposure frequency (days/year);
ED	=	Exposure duration (years);
BW	=	Body weight (kg); and
LT	=	Lifetime (75 years * 365 days/year = 27,375 days).

Ingestion of Fish

$$LADD = [C_{water} * BCF * IngR_{fish} * CF * EF * ED] \setminus [BW * LT]$$

where:

C_{water}	=	Contaminant concentration in water (mg/L);
BCF	=	Bioconcentration factor for PCBs (L/kg);
$IngR_{fish}$	=	Fish ingestion rate (g/day);
CF	=	Conversion factor (0.001 kg/g);
EF	=	Exposure frequency (days/year);
ED	=	Exposure duration (years);
BW	=	Body weight (kg); and
LT	=	Lifetime (75 years * 365 days/year = 27,375 days).

Ingestion of Beef or Other Food Items

$$LADD = [C_{food} * IngR_{food} * EF * ED] \setminus [BW * LT]$$

where:

C_{food}	=	Contaminant concentration in food (mg/g);
$IngR_{food}$	=	Food ingestion rate (g/day);
EF	=	Exposure frequency (days/year);
ED	=	Exposure duration (years);
BW	=	Body weight (kg); and
LT	=	Lifetime (75 years * 365 days/year = 27,375 days).

Incidental Ingestion of PCBs on Surfaces from Hand-to-Mouth Transfer

$$LADD = [C_{surface} * SA * TF * FH * EV * EF * ED] \setminus [BW * LT]$$

where:

$C_{surface}$	=	Contaminant concentration on surface (mg/cm^2);
SA	=	Surface area of the hands exposed (cm^2/event);
TF	=	Fraction of surface PCBs transferred to the skin (unitless);
FH	=	Fraction of hand contacting the mouth (unitless);
EV	=	Daily number of hand-to-mouth events (events/day);

EF = Exposure frequency (days/year);
ED = Exposure duration (years);
BW = Body weight (kg); and
LT = Lifetime (75 years * 365 days/year = 27,375 days).

Inhalation

Inhalation of Vapors or Particulates

$$LADD = [C_{air} * InhR_{air} * ET * ED] \setminus [BW * LT]$$

where:

C_{air} = Contaminant concentration in air as vapors or particulates (mg/m^3);
$InhR_{air}$ = Inhalation rate (m^3/day);
EF = Exposure frequency (days/year);
ED = Exposure duration (years);
BW = Body weight (kg); and
LT = Lifetime (75 years * 365 days/year = 27,375 days);

Dermal Absorption

Dermal Contact with Soil or Sediment

$$LADD = [C_{soil} * SA * AF * CF * ABS * EF * ED] \setminus [BW * LT]$$

where:

C_{soil} = Contaminant concentration in soil (mg/g);
SA = Surface area of the body exposed (cm^2/event);
AF = Amount of soil adhering to the skin (mg/cm^2);
CF = Conversion factor (0.001 g/mg);
ABS = Fraction PCBs absorbed through the skin (0.14; unitless);
EF = Exposure frequency (events/year);
ED = Exposure duration (years);
BW = Body weight (kg); and
LT = Lifetime (75 years * 365 days/year = 27,375 days).

Dermal Contact with Water

$$LADD = [C_{water} * SA * K_p * ET * EF * ED * CF] \setminus [BW * LT]$$

where:

C_{water}	=	Contaminant concentration in water (mg/L);
SA	=	Surface area of the body exposed (cm^2);
K_p	=	Flux of PCBs through the skin (cm/hr);
ET	=	Exposure time (hr/day);
EF	=	Exposure frequency (days/year);
ED	=	Exposure duration (years);
CF	=	Conversion factor (0.001 L/cm^3);
BW	=	Body weight (kg); and
LT	=	Lifetime (75 years * 365 days/year = 27,375 days).

Dermal Contact with Surfaces

$$LADD = [C_{surface} * SA * TF * ABS * EF * ED] \setminus [BW * LT]$$

where:

C_{soil}	=	Contaminant concentration on surface (mg/cm^2);
SA	=	Surface area of the body exposed (cm^2/event);
TF	=	Fraction of surface PCBs transferred to the skin (0.25; unitless);
ABS	=	Fraction of PCBs absorbed through the skin (0.14; unitless);
EF	=	Exposure frequency (events/year);
ED	=	Exposure duration (years);
BW	=	Body weight (kg); and
LT	=	Lifetime (75 years * 365 days/year = 27,375 days).

It should be noted that additional factors may need to be added to these algorithms if the situation warrants it. However, any deviations should be checked carefully by the reviewer to ensure that the factors are logical and correct, and that the units of measure cancel properly to yield an LADD in units of mg/kg/day. It should also be noted that the contaminant concentration terms in the equations above can be measured or modeled values. When modeling is used to predict the concentration term (e.g., air particulate concentrations may be modeled from measured soil

concentrations to estimate inhalation exposure to PCBs in soil after disturbances such as from construction), the reviewer is responsible for ensuring that the algorithms used are accurate and appropriate.

5.7 Accuracy of Exposure/Dose Calculations

The reviewer is responsible for verifying that the exposure estimates presented in the risk assessment document have been calculated correctly. This may be done by spot checking the calculations or by checking all calculations. If spot checking is the selected method for verifying the calculations, a minimum of 10 percent of the exposure estimates should be recalculated for comparison to the estimates provided by the submitter. If errors are observed in the 10 percent checked, it is recommended that the entire risk assessment be checked for mathematical accuracy. Errors found in the calculations should be clearly documented by the reviewer, so that the submitter can correct the errors and resubmit the assessment for a second review.

Verification of the calculations can be conducted using Excel, Lotus or other commercial spreadsheet software, or by using standardized spreadsheets that have been developed by EPA's, Office of Research and Development for some frequently encountered PCB exposure/risk scenarios. These spreadsheets use standard default assumptions for many of the exposure/risk parameters (i.e., contact rate, body weight, etc.) and typical algorithms for calculating risk. Copies of these risk assessment spreadsheets are available from EPA's OPPT/CMD/FOB. As indicated above, another tool that may be useful in checking the exposure/risk assumptions and calculations is the standard risk assessment tables provided in EPA's recently released RAGs Parts D (U.S. EPA, 1998b).

5.8 Appropriateness of Toxicity Values Used

As discussed previously, a total toxicity factor of 4.0 $mg/kg/day^{-1}$ may be used in PCB risk assessments submitted in response to the PCB disposal rule to calculate the risk from both cancer and non-cancer endpoints. This value should be used in conjunction with exposure values, based on total PCBs (i.e., the sum of Aroclor-based concentrations). Dioxin-like PCB congeners are also sometimes evaluated. However, this is not required using the conservative total toxicity factor of 4.0 $mg/kg/day^{-1}$ because it is assumed to account for dioxin-like effects, as well as non-carcinogenic effects of PCBs. If the total toxicity factor of 4.0 $(mg/kg\text{-}day)^{-1}$ for estimating risk from both cancer and non-cancer endpoints is not used, risks may be assessed using the cancer slope factor in EPA/ORD guidance (U.S. EPA, 1996). Non-cancer effects would need to be assessed separately. For some commercial PCB mixtures, toxicity endpoints (i.e., RfDs) are available in EPA's IRIS. If an evaluation of dioxin-like PCBs has been conducted by the assessor, it is likely that the TEQ approach would have been

used. Using this approach, the appropriate congener-specific TEFs (i.e., toxic equivalency factors for 2,3,7,8-tetrachlorinated dibenzo-p-dioxin (TCDD)) are applied, the results are summed, and the cancer slope for 2,3,7,8-TCDD is used. As described in Section 2.6, TEQs are calculated as the product of the PCB congener concentration and the congener-specific TEF. The TEFs for the dioxin-like congeners were presented in Table 6. The toxicity of 2,3,7,8-TCDD is currently being reassessed by EPA. Its most current cancer slope factor can be retrieved from EPA's IRIS or HEAST.

5.9 Accuracy of Risk Calculations

As indicated above for the exposure calculations, the risk assessment reviewer must verify that the risk calculations have been carried out correctly. This may be done by checking all or a portion of the values. Cancer risks are assessed by multiplying the exposure values by the cancer slope value. Thus, for cancer risks involving the sum of PCB Aroclors:

Cancer Risk = Exposure (i.e., CDI or LADD; mg/kg/day) * slope factor.

Total risk is calculated in a similar fashion if the total toxicity factor for PCBs of 4.0 $mg/kg/day^{-1}$ is used.

For dioxin-like congeners, cancer risks would be:

Cancer Risk = TEQ Exposure (i.e., CDI or LADD; mg/kg/day) * SF for TCDD in $mg/kg/day^{-1}$, as provided in IRIS.

Noncarcinogenic effects would be calculated as:

Hazard = Exposure / 2E-5 mg/kg/day for Aroclor 1254,

or

Hazard = Exposure / 7E-5 mg/kg/day for Aroclor 1016.

5.10 Adequacy of Uncertainty Assessment

A key component of the risk characterization is the presentation of uncertainties associated with the assessment. As indicated in Section 4.2.5, uncertainties can occur as a result of sampling, fate and transport factors, population variability, exposure scenarios and assumptions, and the toxicity data used. PCB risk assessments should provide detailed explanations of the inherent uncertainties associated with the assessments including the likely direction of biases that these uncertainties may

cause. The reviewer must ensure that the uncertainties associated with the assessment are adequately characterized, and make recommendations as to whether or not these uncertainties are significant enough to preclude the use of the risk assessment in making risk management decisions with regard to the site.

5.11 Appropriateness of Risk Interpretation and Conclusions

Directly related to the uncertainty assessment, is the interpretation of risks and conclusions reached by the submitter. This is the final step of the risk assessment review. The reviewer needs to determine whether the risks associated with the site have been properly interpreted and that the risks have been adequately characterized. Decisions regarding the risk characterization should take into account the results of the previous stages of the review. For example, if the risks were calculated correctly, but the sampling data used to estimate the exposure concentration were inadequate, the risk conclusions may be compromised, and the interpretations made by the submitter may not be appropriate for use in risk management decisions. This may also be the case if improper exposure assumptions or toxicity values were used. If the risks have been adequately and correctly characterized, the risk assessment should be accepted and the results should be included in the PCB Risk Assessment Review Data Base that is being developed by OPPT/NPCD/FOB for the purposes of tracking PCB risk assessments conducted in response to the PCB disposal rule.

5.12 Other Factors

Although standard methods for conducting/reviewing PCB risk assessments have been outlined in this document, some risk assessments may have components that require the use of non-standard reference materials, unique exposure scenarios or assumptions, or require the use of unconventional methods for estimating risks. These risk assessments will need to be assessed on a case-by-case basis. It is recommended that when non-standard methods are used, the submitter provide all of the necessary reference materials and estimation tools to allow the reviewer to adequately evaluate the methods.

6.0 RISK ASSESSMENT REVIEW TEMPLATE

A risk assessment review template has been developed to assist reviewers in completing the review process in a standardized manner. The template is presented on the following pages. The template will be available in electronic format which will allow for computerized data entry, printing, and incorporation into the PCB Risk Assessment Review Data Base. The template requires three types of entries, depending on the particular component of the review. These entries include Yes/No check boxes, selections from a "pick list" of answers, and text entries. In most cases, the reviewer is prompted to answer specific questions regarding the risk assessment document. Questions requiring the reviewer to select from a "pick list" allow for more than one item to be selected, if necessary. In most cases an "other" category is also included along with a text box for further explanation of unique entries. This allows the reviewer to capture any additional information needed to explain these entries. The reviewer is encouraged to fully complete the template. Some items of information are required (e.g., each risk assessment will be assigned a unique identification number that will need to be included on the review; the name and affiliation of the reviewer will also be included) before the reviewer can proceed, others do not require an answer, but will diminish the usefulness of the review if they are left unanswered. Help screens will be available on the electronic version of the template, when programming is complete.

A hard copy of the template is shown on the following pages.

General Information

Risk Assessment Review Identification Number:		Date of Review:	
Facility Name:		**EPA ID:**	
Facility Address:			
City:		**State:**	**Zip Code:**
Risk Assessment Point of Contact (POC):			
POC Affiliation:			
POC Phone Number:		Date of Risk Assessment:	

Evaluation Questions

1.Site Overview

	Yes	No
a. Were the site-specific objectives clearly stated?	○	○
b. Was scope of assessment described (i.e., type and complexity of risk assessment)?	○	○
c. Was history of site activities provided?	○	○
d. Was site map provided?	○	○
e. Was nature of contamination described (i.e., media, contaminant levels)?	○	○
f. Was site conceptual model provided?	○	○

Provide Brief Site Summary

2. Adequacy of Data

	Yes	No
a. Were data quality objectives clearly defined?	○	○
b. Were all appropriate media sampled?	○	○

If no to 2b, please explain:

2. Adequacy of Data (continued)

c. What media were sampled (check all that apply)?

☐ 1) Groundwater	☐ 8) Liquid Waste
☐ 2) Leachate	☐ 9) Solid Waste
☐ 3) Sediment	☐ 10) Air
☐ 4) Sludge	☐ 11) Surface Soil
☐ 5) Soil	☐ 12) Subsurface Soil
☐ 6) Surface Water	☐ 13) Hard Surfaces
☐ 7) Debris	☐ 14) Other Specify:

	Yes	No
d. Was adequate justification provided for media not sampled?	○	○
e. Were sampling locations consistent with the nature of the PCB contamination (e.g., at an appropriate depth, or along the path of migration)?	○	○

If no to 2e, please explain:

	Yes	No
f. Were details about the sampling strategy provided (i.e., site map with sampling locations, numbers, etc.)?	○	○
g. Was the sampling strategy representative of the site in terms of size and distribution of samples throughout the site?	○	○

If no to 2g, please explain:

	Yes	No
h. Were appropriate QA/QC measures used in sampling (i.e., field blanks, duplicate samples)?	○	○

If no to 2h, please explain:

2. Adequacy of Data (continued)

i. For what category of PCBs were samples analyzed (check all that apply)?

☐ 1) Total PCBs	☐ 6) Aroclor 1248	☐ 11) Congener-Specific
☐ 2) Aroclor 1016	☐ 7) Aroclor 1254	PCB 77 PCB 105 PCB 114 PCB 118 PCB 123 PCB 126
☐ 3) Aroclor 1221	☐ 8) Aroclor 1260	
☐ 4) Aroclor 1232	☐ 9) Aroclor 1262	
☐ 5) Aroclor 1242	☐ 10) Aroclor 1268	

	Yes	No
j. Were appropriate analytical methods used?	○	○
k. Were the detection limits sufficiently low to allow for the detection of risks at the target risk level?	○	○
l. Were qualified data used correctly?	○	○

If no to 2k or 2l, please explain:

	Yes	No
m. Was one-half the detection limit used as a proxy concentration for samples with non-detected PCBs?	○	○

3. Available Data

a. What was the maximum concentration associated with each type of media?

Soil	Total PCBs	Concentration (ppm)
Groundwater Leachate Sediment	Aroclor 1016 Aroclor 1221 Aroclor 1232	

b. What was the average concentration associated with each type of media?

Soil	Total PCBs	Concentration (ppm)
Groundwater Leachate Sediment	Aroclor 1016 Aroclor 1221 Aroclor 1232	

3. Available Data (continued)

c. What was the 95 UCL concentration associated with each type of media?

Soil	Total PCBs	Concentration (ppm)
Groundwater Leachate Sediment	Aroclor 1016 Aroclor 1221 Aroclor 1232	

d. Which value was used as the exposure point concentration in the risk assessment?

Soil	Total PCBs	Concentration
Groundwater Leachate Sediment	Aroclor 1016 Aroclor 1221 Aroclor 1232	Maximum

4. Exposure Assessment

	Yes	No
a. Were all relevant, potentially exposed populations considered?	○	○

If no to 4a, please explain:

b. Were there any important subpopulations (check all that apply)?

☐ 1) Sport Fishermen ☐ 2) Subsistence Fishermen

☐ 3) Other Specify:

c. What are the current populations at or near the site (check all that apply)?

☐ 1) Residential, Adult	☐ 5) Recreational, Child	☐ 9) Construction
☐ 2) Residential, Child	☐ 6) Agricultural	☐ 10) Other
☐ 3) Industrial / Commercial	☐ 7) Educational	Specify:
☐ 4) Recreational, Adult	☐ 8) Military	☐ 11) None

d. What are the future populations at or near the site (check all that apply)?

☐ 1) Residential, Adult	☐ 5) Recreational, Child	☐ 9) Construction
☐ 2) Residential, Child	☐ 6) Agricultural	☐ 10) Other
☐ 3) Industrial / Commercial	☐ 7) Educational	Specify:
☐ 4) Recreational, Adult	☐ 8) Military	☐ 11) None

4. Exposure Assessment (continued)

e. What exposure descriptors were considered (check all that apply)?

☐ 1) Reasonable Maximum Exposure

☐ 2) Central Tendancy Exposure ☐ 3) Other Specify: ☐

f. What current exposure scenarios were considered (check all that apply)?

Soil	Residential, Adult	
Groundwater	Residential, Child	Ingestion ☐
Surfacewater	Industrial / Commercial	Inhalation ☐
Air	Construction	Dermal ☐

g. What future exposure scenarios were considered (check all that apply)?

Soil	Residential, Child	
Groundwater	Recreational, Child	Ingestion ☐
Surfacewater	Agricultural	Inhalation ☐
Air	Educational	Dermal ☐

	Yes	No
h. Were the appropriate exposure algorithms used?	○	○

If no to 4h, please explain:

	Yes	No
i. Were appropriate standard recommended exposure values used?	○	○

If no to 4i, please explain:

	Yes	No
j. Were exposure calculations completed correctly?	○	○

k. What percentage of the calculations were checked? ☐

5. Risk Characterization

	Yes	No
a. Were the appropriate toxicity values used?	○	○

If no to 5a, please explain:

	Yes	No
b. Were risk calculations completed correctly?	○	○

If no to 5b, please explain:

c. What percentage of the calculations were checked?

d. What are the current risk levels for the media / pathways / populations of interest?

Soil	Residential, Adult	Ingestion	Risk Level
Groundwater Surfacewater Air	Residential, Child Industrial / Commercial Construction	Inhalation Dermal	

e. What are the future risk levels for the media / pathways / populations of interest?

Soil	Residential, Child	Ingestion	Risk Level
Groundwater Surfacewater Air	Recreational, Child Agricultural Educational	Inhalation Dermal	

	Yes	No
f. Were risks summed across all pathways?	○	○

g. What was the current total risk for each population at or near the site?

Residential, Adult	Total Risk
Residential, Child Industrial / Commercial Construction	

5. Risk Characterization (continued)

g. What was the future total risk for each population at or near the site?

Residential, Child

- Recreational, Child
- Agricultural
- Educational

Total Risk

6. Uncertainty Assessment

	Yes	No
a. Were the sources of uncertainty adequately characterized?	○	○

If no to 6a, please explain:

	Yes	No
b. Are the risk interpretations and conclusions consistent with the data presented?	○	○

If no to 6b, please explain:

	Yes	No
c. Is the risk assessment documentation adequate?	○	○

If no to 6c, please explain:

	Yes	No
d. Are there any other factors used in the development of the risk assessment that need further explanation?	○	○

If yes to 6d, please explain:

6. Uncertainty Assessment (continued)

	Yes	No
e. Is the overall risk assessment deemed adequate for making risk management decisions at the site?	○	○

f. What is the selected remedy at the site?

☐ Groundwater - Pump and Treat	☐ Groundwater - Containment	☐ Groundwater - Natural Attenuation
☐ On-site Treatment	☐ On-site Disposal	☐ On-site Containment
☐ Off-site Treatment	☐ Off-site Disposal	☐ Off-site Containment
☐ Institutional Controls	☐ No Further Action	☐ Other Specify:
☐ No Action		

Risk Assessment Review Comments

Table 1. PCB Congeners and their IUPAC Numbers

PCB Congener	IUPAC Number
Tri-chlorobiphenyls (TrCBs)	
2,5,2'-TrCB	18
3,4,4'-TrCB	37
Tetra-chlorobiphenyls (TeCBs)	
2,3,2',5'-TeCB	44
2,4,2',5'-TeCB	49
2,5,2',5-TeCB	52
2,5,3',4'-TeCB	70
2,4,5,4'-TeCB	74
3,4,3',4'-TeCB	77
3,4,5,4'-TeCB	81
Penta-chlorobiphenyls (PeCBs)	
2,3,4,2',5'-PeCB	87
2,4,5,2',4'-PeCB	99
2,4,5,2',5'-PeCB	101
2,3,4,3',4'-PeCB	105
2,3,4,5,4'-PeCB	114
2,4,5,3',4'-PeCB	118
2,4,6,3',4'-PeCB	119
3,4,5,2',4'-PeCB	123
3,4,5,3',4'-PeCB	126
Hexa-chlorobiphenyls (HxCBs)	
2,3,4,2',3',4'-HxCB	128
2,3,4,2',4',5'-HxCB	138
2,3,5,6,2',5'-HxCB	151
2,4,5,2',4',5'-HxCB	153
2,3,4,5,3',4'-HxCB	156
2,3,4,3',4',5'-HxCB	157
2,3,4,3',4',6'-HxCB	158
2,4,5,3',4',5'-HxCB	167
2,4,6,3',4',5'-HxCB	168
3,4,5,3',4',5'-HxCB	169
Hepta-chlorobiphenyls (HxCBs)	
2,3,4,5,2',3',4'-HpCB	170
2,3,5,6,2',3',4'-HpCB	177
2,3,4,5,2',4',5'-HpCB	180
2,3,4,6,2',4',5'-HpCB	183
2,3,5,6,2',4',5'-HpCB	187
2,3,4,5,3',4',5'-HpCB	189
Octa-chlorobiphenyls (OCBs)	
2,3,4,5,2',3',4',5'-OCB	194
2,3,4,5,2',3',5',6'-OCB	201

Source: U.S. EPA (1996)

Table 2. Typical Composition (%) of Some Commercial PCB Mixtures

	Aroclor					Clophen		Kanechlor		
	1016	1242	1248	1254	1260	A30	A60	300	400	500
Mono-CBs	2	1	-	-	-	-	-	-	-	-
Di-CBs	19	13	1	-	-	20	-	17	3	-
Tri-CBs	57	45	21	1	-	52	-	60	33	5
Tetra-CBs	22	31	49	15	-	22	1	23	44	26
Penta-CBs	-	10	27	53	12	3	16	1	16	55
Hexa-CBs	-	-	2	26	42	1	51	-	5	13
Hepta-CBs	-	-	-	4	38	-	28	-	-	-
Octa-CBs	-	-	-	-	7	-	4	-	-	-
Nona-Cbs	-	-	-	-	1	-	-	-	-	-
Deca-CBs	-	-	-	-	-	-	-	-	-	-

Source: U.S. EPA (1996)

Table 3. Releases of PCBs Reported in TRI (1988-1993)

Year	No. of TRI Forms Filed	Reported Releases (kg)					
		Fugitive or Nonpoint Air Emissions	Stack or Point Air Emissions	Surface Water Discharges	Underground Injection	Releases to Land	TOTAL RELEASES
1993	16	0	0	0	0	120	120
1992	20	0	0	0	0	0.5	0.5
1991	26	0	0	0	0	0	0
1990	NA	2.3	0	0	0	32,372	32,374
1989	NA	0	0	120	0	453	573
1988	122	2.7	0	4.5	0	341	348

Sources: U.S. EPA (1993); U.S. EPA (1995a)

NA = Not available.

Table 4. Offsite Transfers of PCBs Reported in TRI (1988-1993)

Year	No. of TRI Forms Filed	Reported Transfers (kg)		
		Transfers to POTWs	Transfers for Treatment/ Disposal	TOTAL TRANSFERS
1993	16	120	463,385	463,505
1992	20	0	766,638	766,638
1991	26	0	402,535	402,535
1990	NA	0	1,181,961	1,181,961
1989	NA	0.5	2,002,237	2,002,237
1988	122	113	2,642,133	2,642,246

kg = kilograms.
POTWs = publicly-owned treatment works.

Sources: U.S. EPA (1993); U.S. EPA (1995a)

NA = Not available.

Table 5. Physical/chemical Properties of PCB Aroclors

Aroclor	Molecular Weight (g/mole)[a]	Solubility (mg/L)[a]	Vapor Pressure (mmHg at 25°C)[a]	Henry's Law Constant (atm-m^3/mol at 25°C)[a]	K_{oc}[b]	K_{ow}[a]
1016	257.9	0.42 (25°C)	4.00×10^{-4}	2.9×10^{-4}	180,000	5.6
1221	200.7	0.59 (24°C)	6.70×10^{-3}	3.5×10^{-3}	5,800	4.7
1232	232.2	0.45 (25°C)	4.06×10^{-3}	-	771	5.1
1242	266.5	0.34 (25°C)	4.06×10^{-4}	5.2×10^{-4}	6,300	5.6
1248	299.5	0.06 (24°C)	4.94×10^{-4}	2.8×10^{-3}	277,000	6.2
1254	328	0.057 (24°C)	7.71×10^{-5}	2.0×10^{-3}	530,000	6.5
1260	375.7	0.08 (24°C)	4.05×10^{-5}	4.6×10^{-3}	6,700,000	6.8
1262	389	0.052 (24°C)	-	-	-	-
1268	453	0.30 (24°C)	-	-	-	-

[a] Source: ATSDR (1996)
[b] Source: U.S. EPA (1982)

Table 6. Toxic Equivalency Factors (TEFs) for Dioxin-like PCBs

PCB Congener	TEF
3,4,3',4'-TeCB (IUPAC 77)	0.0005
2,3,4,3',4'-PeCB (IUPAC 105)	0.0001
2,3,4,5,4'-PeCB (IUPAC 114)	0.0005
2,4,5,3',4'-PeCB (IUPAC 118)	0.0001
3,4,5,2',4'-PeCB (IUPAC 123)	0.0001
3,4,5,3',4'-PeCB (IUPAC 126)	0.1
2,3,4,5,3'4'-HxCB (IUPAC 156)	0.0005
2,3,4,3',4',5'-HxCB (IUPAC 157)	0.0005
2,4,5,3',4',5'-HxCB (IUPAC 167)	0.00001
3,4,5,3',4',5'-HxCB (IUPAC 169)	0.01
2,3,4,5,2',3',4'-HpCB (IUPAC 170)	0.0001
2,3,4,5,2',4',5'-HpCB (IUPAC 180)	0.00001
2,3,4,5,3',4',5'-HpCB (IUPAC 189)	0.0001

Source: Ahlborg et al. (1994); U.S. EPA (1994a)

Table 7. Summary of Exposure Factor Recommendations and Confidence Ratings

EXPOSURE FACTOR	RECOMMENDATION	CONFIDENCE RATING
Drinking water intake rate	21 ml/kg-day/1.4 L/day (average) 34 ml/kg-day/2.3 L/day (90th percentile) Percentiles and distribution also included Means and percentiles also included for pregnant and lactating women	Medium Medium
Total fruit intake rate	3.4 g/kg-day (per capita average) 12.4 g/kg-day (per capita 95th percentile) Percentiles also included Means presented for individual fruits	Medium Low
Total vegetable intake rate	4.3 g/kg-day (per capita average) 10 g/kg-day (per capita 95th percentile) Percentiles also included Means presented for individual vegetables	Medium Low
Total meat intake rate	2.1 g/kg-day (per capita average) 5.1 g/kg-day (per capita 95th percentile) Percentiles also included Percentiles also presented for individual meats	Medium Low
Total dairy intake rate	8.0 g/kg-day (per capita average) 29.7 g/kg-day (per capita 95th percentile) Percentiles also included Means presented for individual dairy products	Medium Low
Grain intake	4.1 g/kg-day (per capita average) 10.8 g/kg-day (per capita 95th percentile) Percentiles also included	High Low in long-term upper percentiles
Breast milk intake rate	742 ml/day (average) 1,033 ml/day (upper percentile)	Medium Medium
Fish intake rate	General Population 20.1 g/day (total fish) average 14.1 g/day (marine) average 6.0 g/day (freshwater/estuarine)average 63 g/day (total fish) 95th percentile long-term Percentiles also included Serving size 129 g (average) 326 g (95th percentile) Recreational marine anglers 2 - 7 g/day (finfish only) Recreational freshwater 8 g/day (average) 25 g/day (95th percentile) Native American Subsistence Population 70 g/day (average) 170 g/day (95th percentile)	 High High High Medium High High Medium Medium Medium Medium Low

Table 7. Summary of Exposure Factor Recommendations and Confidence Ratings (continued)

EXPOSURE FACTOR	RECOMMENDATION	CONFIDENCE RATING
Home produced food intake	Total Fruits 2.7 g/kg-day (consumer only average) 11.1 g/kg-day (consumer only 95th percentile) Percentiles also included Total vegetables 2.1 g/kg-day (consumer only average) 7.5 g/kg-day (consumer only 95th percentile) Percentiles also included Total meats 2.2 g/kg-day (consumer only average) 6.8 g/kg-day (consumer only 95th percentile) Percentiles also included Total dairy products 14 g/kg-day (consumer only average) 44 g/kg-day (consumer only 95th percentile) Percentiles also included	Medium (for means and short-term distributions) Low (for long-term distributions)
Inhalation rate	Children (<1 year) 4.5 m^3/day (average) Children (1-12 years) 8.7 m^3/day (average) Adult Females 11.3 m^3/day (average) Adult Males 15.2 m^3/day (average)	High High High High
Surface area	Water contact (bathing and swimming) Use total body surface area for children in Tables 6-6 through 6-8; for adults use Tables 6-2 through 6-4 (percentiles are included) Soil contact (outdoor activities) Use whole body part area based on Table 6-6 through 6-8 for children and 6-2 through 6-4 for adults (percentiles are included)	High High
Soil adherence	Use values presented in Table 6-16 depending on activity and body part (central estimates only)	Low
Soil ingestion rate	Children 100 mg/day (average) 400 mg/day (upper percentile) Adults 50 mg/day (average) Pica child 10 g/day	Medium Low Low
Life expectancy	75 years	High
Body weight for adults	71.8 kg Percentiles also presented in tables 7-4 and 7-5	High
Body weights for children	Use values presented in Tables 7-6 and 7-7 (mean and percentiles)	High
Body weights for infants (birth to 6 months)	Use values presented in Table 7-1 (percentiles)	High

Table 7. Summary of Exposure Factor Recommendations and Confidence Ratings (continued)

EXPOSURE FACTOR	RECOMMENDATION	CONFIDENCE RATING
Showering/Bathing	Showering time	High
	10 min/day (average)	
	35 min/day (95th percentile)	
	(percentiles are also included)	
	Bathing time	High
	20 min/event (median)	
	45 min/event (90th percentile)	
	Bathing/showering frequency	High
	1 shower event/day	
Swimming	Frequency	High
	1 event/month	
	Duration	High
	60 min/event (median)	
	180 min/event (90th percentile)	
Time indoors	Children (ages 3-11)	Medium
	19 hr/day (weekdays)	
	17 hr/day (weekends)	
	Adults (ages 12 and older)	Medium
	21 hr/day	
	Residential	High
	16.4 hrs/day	
Time outdoors	Children (ages 3-11)	Medium
	5 hr/day (weekdays)	
	7 hr/day (weekends)	
	Adults	Medium
	1.5 hr/day	
	Residential	High
	2 hrs/day	
Time spent inside vehicle	Adults	
	1 hr 20 min/day	Medium
Occupational tenure	6.6 years (16 years old and older)	High
Population mobility	9 years (average)	Medium
	30 years (95th percentile)	Medium
Residence volume	369 m^3 (average)	Medium
	217 m^3 (conservative)	Medium
Residential air exchange	0.45 (median)	Low
	0.18 (conservative)	Low

Note: Confidence rating refers to the quantity and quality of studies upon which the recommendations are based. Refer to U.S. EPA (1997) for additional information about these ratings.

Source: Exposure Factors Handbook (U.S. EPA, 1997).

Table 8. EPA's Weight-of-evidence Classification for Carcinogens

Group	Description
A	Human carcinogen
B1	Probable human carcinogen; limited human data available
B2	Probable human carcinogen; sufficient evidence in animals and inadequate or no evidence in humans
C	Possible human carcinogen
D	Not classifiable as to human carcinogenicity
E	Evidence on noncarcinogenicity in humans

Source: U.S. EPA (1989)

Table 9. Slope Factors, Based on EPA/ORD's Cancer Dose-Response Assessment

Tier	Definition for Use	Slope Factor $(mg/kg/day)^{-1}$
1 (high risk and persistence)	This value should be used as a default value when information on the mixture of PCBs is limited. It "is appropriate for food chain exposure, sediment and soil ingestion, and dust or aerosol inhalation; these are exposure pathways for which environmental processes are likely to increase risk." This value is also used for all early-life exposure.	2.0 (upper-bound) 1.0 (central-estimate)
2 (low risk and persistence)	This value" is appropriate for drinking water ingestion and vapor inhalation; these are exposure pathways for which environmental processes are likely to decrease risk."	0.4 (upper-bound) 0.3 (central-estimate)
3 (lowest risk and persistence)	This value "can be used when there are congener or isomer analyses for the mixture of interest...and if these analyses verify that congeners with more than four chlorines comprise less than one-half percent of total PCBs, as well as the absence of dioxin-like, tumor-promoting, and persistent congeners. "It should not be used without information on the congener composition of the mixture."	0.07 (upper-bound) 0.04 (central-estimate)

Source: Derived from U.S. EPA (1996)

Table 10. Relationship Between Excess Cancer Risk and Cancer Cases in a Defined Population

Excess Lifetime Cancer Risk	Excess Lifetime Cancer Cases	Excess Annual Cancer Cases in a Population of 250 Million[a]
1×10^{-1}	1 out of 10 persons	330,000
1×10^{-2}	1 out of 100 persons	33,000
1×10^{-3}	1 out of 1,000 persons	3,300
1×10^{-4}	1 out of 10,000 persons	330
1×10^{-5}	1 out of 100,000 persons	33
1×10^{-6}	1 out of 1,000,000 persons	3

[a] Excess annual cancer cases = (excess lifetime cancer risk * 250,000,000 persons) / 75 year lifetime.

Table 11. Analytical Methods for Polychlorobiphenyls[a]

Targeted Media	Analytical Method	Reference
Groundwater, soils, sludges, non-water miscible wastes and other solid and aqueous matrices	SW-846 Method 8082[b]	Test Methods for Evaluating Solid Wastes Physical/Chemical updates through Update III December 1996.
Groundwater and finished drinking water	EPA 500 Series Method 508	Methods for the Determination of Organic Compounds in Drinking Water, EPA/600/4-88/039, December 1988 and Supplement 1, EPA/600/4-90/020 1990.
Municipal and industrial discharge	EPA 600 Series Method 608	40 CFR, Part 136, July 1, 1988.
Drinking water, surface and groundwater, municipal and industrial discharges	Standard Methods 6630	Standard Methods for the Examination of Water and Waste Water, 18th Edition 1992.
Water, soil, and sediment	CLP PEST (Organic SOW)	Contract Laboratory Program - Statement of Work for Organic Analysis, Multi-Media Multi-Concentration. Document ILMO2 - ILMO3.0, 1992
Solid wastes, soil, air sampling media, and water	SW-846 Method 8270	Test Methods for Evaluating Solid Wastes Physical/Chemical updates through Update III December 1996.
Soils, sludges, and non-water miscible wastes	SW-846 Method 8275[c]	Test Methods for Evaluating Solid Wastes Physical/Chemical updates through Update III December 1996.
Groundwater and raw source water	EPA 500 Series Method 525.1	Methods for the Determination of Organic Compounds in Drinking Water, EPA/600/4-88/039, December 1988 and Supplement 1, EPA/600/4-90/020 1990.
Wastewater	EPA 600 Series Method 625	40 CFR, Part 136, July 1, 1988.
Domestic, industrial wastewaters, natural and potable waters	Standard Methods 6410	Standard Methods for the Examination of Water and Waste Water, 18th Edition 1992.
Water, soil, and sediment	CLP SVOA (Organic SOW)	Contract Laboratory Program - Statement of Work for Organic Analysis, Multi-Media Multi-Concentration. Document ILMO2 - ILMO3.0, 1992
Air	Method 5503, Issue 2	NIOSH Manual of Analytical Methods, 4th Edition, August 15, 1994.
Serum	Method 8004, Issue 2	NIOSH Manual of Analytical Methods, 4th Edition, August 15, 1994.

[a] Unless otherwise indicated, the methods listed report only individual aroclors.
[b] This method can report either aroclors or individual congeners.
[c] This method reports individual congeners.

Table 12. Data Qualifiers and Their Potential Use in Quantitative Risk Assessment

Qualifier	Definition	Indicates:		Include Data in Quantitative Risk Assessment?
		Uncertain Identity?	Uncertain Concentration?	
Inorganic Chemical Data (CLP Qualifiers)				
B	Reported value is <CRDL, but >IDL	No	?	Yes
U	Compound was analyzed for, but not detected	Yes	Yes	?
E	Value is estimated due to matrix interferences	No	Yes	Yes
M	Duplicate injection precision criteria not met	No	Yes	Yes
N	Spiked sample recovery not within control limits	No	Yes	Yes
S	Reported value was determined by the Method of Standard Additions (MSA)	No	No	Yes
W	Post-digestion spike for furnace AA analysis is out of control limits, while sample absorbance is <50% of spike absorbance	No	Yes	Yes
✹	Duplicate analysis was not within control limits	No	Yes	Yes
+	Correlation coefficient for MSA was <0.995	No	Yes	Yes
Organic Chemical Data (CLP Qualifiers)				
U	Compound was analyzed for, but not detected	Yes	Yes	?
J	Value is estimated, either for a tentatively identified compound (TIC) or when a compound is present (spectral identification criteria are met, but the value is <CRQL)	No, for TCL chemicals; Yes, for TICs	Yes	?
C	Pesticide results were confirmed by GC/MS	No	No	Yes
B	Analyte found in associated blank as well as in sample	No	Yes	Yes
E	Concentration exceeds calibration range of GC/MS instrument	No	Yes	Yes
D	Compound identified in an analysis at a secondary dilution factor	No	No	Yes
A	The TIC is a suspected aldolcondensation product	Yes	Yes	No
X	Additional flags defined separately	--	--	--
Inorganic and Organic Chemical Data (Validation Qualifiers)				
U	The material was analyzed for, but not detected. The associated numerical value is the SQL.	Yes	Yes	?
J	The associated numerical value is an estimated quantity	No	Yes	Yes
R	Quality control indicates that the data are unusable (compound may or may not be present). Re-sampling and/or re-analysis is necessary for verification.	Yes	Yes	No
Z	No analytical result (inorganic data only)	--	--	--
Q	No analytical result (organic data only)	--	--	--
N	Presumptive evidence of presence of material (tentative identification)	Yes	Yes	?

Source: U.S. EPA, 1989

Table 13. Key Exposure Pathways

	Ingestion	Inhalation	Dermal Absorption
Soil/Sediment	Incidental ingestion of soil/sediment	Inhalation of soil vapors Inhalation of disturbed soil as dust particulates	Direct contact with soils/ sediments
Surface Water	Ingestion of drinking water Ingestion of fish tissue Incidental ingestion while wading or swimming	Inhalation of vapors during showering Inhalation of vapors while swimming or wading	Dermal absorption while swimming or wading Dermal absorption while showering
Groundwater	Ingestion of drinking water	Inhalation of vapors during showering	Dermal absorption while showering
Foods	Ingestion of food items	--	--
Surface Contamination	Incidental ingestion from hand-to-mouth contact	Inhalation of PCBs offgassing from surfaces	Direct contact with PCB contaminated surfaces

7.0 REFERENCES

Ahlborg, V.G.; Becking, G.C.; Birnbaum, L.S.; Brower, A.; Derks, H.J.G.M.; Feeley, M.; Golor, C.; Hanberg, A.; Larsen, J.C.; Liem, A.K.D.; Safe, S.H.; Schlatter, C.; Waern, F.; Younes, M.; Yränkeikki, E. (1994) Toxic equivalency factors for dioxin-like PCBs. Chemosphere 28(6):1049-1067.

ATSDR (1996) Toxicological Profile for Polychlorinated Byphenyls. Draft. Atlanta, Georgia: Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services.

Christianson, H.; Stoltz, M.; Erickson, M.D. (1986) Dermal Transfer of PCBs from Surfaces. Washington, DC: U.S. Environmental Protection Agency, Office of Toxic Substances. USEPA Contract No. 68-02-3938, Task No. 37.

Gilbert, R.O. (1987) Statistical Methods for Environmental Pollution Monitoring. New York, Van Nostrand Reinhold.

Klassen, C.D.; Amdur, M.O.; Doull, J. (1986) Casarett and Doull's Toxicology: The Basic Science of Poisons. New York: Macmillan Publishing Co.

Lyman, W.J.; Reehl, W.F.; Rosenblatt, D.H. (1982) Handbook of Chemical Property Estimation Methods; Environmental Behavior of Organic Compounds. McGraw-Hill Book Company, New York.

NRC (1983) Risk Assessment in the Federal Government: Managing the Process. Washington, DC: National Research Council of the National Academy of Sciences and the National Academy of Engineering.

Schecter, A. (1991) Dioxins and Related Chemicals in Humans and in the Environment. In: Gallo, M.; Scheuplein, R.; Van der Heijden, K. eds. Biological basis for risk assessment of dioxins and related compounds. Banbury Report #35. Plainview, NY: Cold Spring Harbor Laboratory Press.

U.S. Environmental Protection Agency (1982) Aquatic Fate Process Data for Organic Priority Pollutants. Washington, D.C.: U.S. Environmental Protection Agency, Office of Water.

U.S. Environmental Protection Agency (1987a) Locating and Estimating Air Emissions from Sources of Polychlorinated Biphenyls (PCB). Research Triangle Park, NC: Office of Air Quality Planning and Standards, EPA-450/4-84-007n.

U.S. Environmental Protection Agency (1987b) Polychlorinated Biphenyls Spill Cleanup Policy. Federal Register, Vol. 52, No. 63, pp. 10688-10710, dated April 2, 1987. U.S. Environmental Protection Agency.

U.S. EPA (1989) Risk Assessment Guidance for Superfund, Volume I - Human Health Evaluation Manual, Part A. Washington, D.C.: U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. EPA/540/1-89/002.

U.S. EPA (1990) National Oil and Hazardous Substances Pollution Contingency Plan; Final Rule. Washington D.C.: U.S. Environmental Protection Agency. *Federal Register*. 55 FR 8666.

U.S. EPA (1991a) Risk Assessment Guidance for Superfund, Volume I - Human Health Evaluation Manual, Part B, Development of Risk-Based Preliminary Remediation Goals.

U.S. EPA (1991b) Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual, Part C - Risk Evaluation of Remedial Alternatives.

U.S. EPA (1992a) Guidelines for Exposure Assessment. Washington, D.C.: U.S. Environmental Protection Agency. Federal Register. 57 FR 22888.

U.S EPA (1992b) Dermal Exposure Assessment: Principles and Applications. Washington, D.C.: Office of Health and Environmental Assessments. EPA/600/8-9/001F.

U.S. EPA (1992c) Guiance for Data Usability in Risk Assessment (Part A). Washingtom, D.C.: U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. Publication No. 9285.7-09A.

U.S. Environmental Protection Agency (1993) 1991 Toxics release Inventory - Public Data Release. Washington, DC: Office of Pollution Prevention and Toxics. EPA-745-R-93-003.

U.S. EPA (1994a) Estimating Exposure to Dioxin-like Compounds, Draft. Washington D.C.: U.S. Environmental Protection Agency, Office of Research and Development.

U.S. EPA (1994b) Proposed PCB Disposal Rule. Federal Register, December 6, 1994. U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency (1995a) 1993 Toxics release inventory - public data release. Washington, DC: Office of Pollution Prevention and Toxics. EPA-745-R-95-010.

U.S. EPA (1995b) Soil Screening Guidance: Technical Background Document.

U.S. EPA (1996) PCBs: Cancer Dose Assessment and Application to Environmental Mixtures. Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development. EPA/600/P-96/001.

U.S. EPA (1997) Exposure Factors Handbook. Washington, D.C.: U.S. Environmental Protection Agency, Office of Health and Environmental Assessment. EPA/600/8-89/043.

U.S. EPA (1998a) Integrated Risk Information System (IRIS) Database. Washington, D.C.: U.S. Environmental Protection Agency.

U.S. EPA (1998b) Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments. Washington, D.C.: U.S. Environmental Protection Agency, Office of Emergency and Remedial Response.

Versar, Inc. (1976) PCBs in the United States: Industrial Use and Environmental Distribution. Washington, DC: U.S. Environmental Protection Agency, Office of Toxic Substances. EPA Contract No. 68-01-3259, Task I.

Wester, R.; Maibach, H.; Sedik, L.; Melendres, J. (1993) Percutaneous Absorption of PCBs from Soil: *in vivo* Rhesus Monkey, *in vitro* Human Skin, and Binding to Powdered Human Stratum Corneum. J. Toxicol. Environ. Health. 39:375-82.

GLOSSARY

Absorption fraction (percent absorbed) - The relative amount of a substance that penetrates through a barrier into the body, reported as a unitless fraction.

Accuracy - The measure of the correctness of data, as given by the difference between the measured value and the true or standard value.

Ambient - The conditions surrounding a person, sampling location, etc.

Analytical uncertainty propagation - Examines how uncertainty in individual parameters affects the overall uncertainty of the exposure assessment. The uncertainties associated with various parameters may propagate through a model very differently, even if they have approximately the same uncertainty. Since uncertainty propagation is a function of both the data and the model structure, this procedure evaluates both input variances and model sensitivity.

Average - The sum of a set of observations divided by the number of observations.

Average daily dose - Dose rate averaged over a pathway-specific period of exposure expressed as a daily dose on a per-unit-body-weight basis. The ADD is used for exposure to chemicals with non-carcinogenic non-chronic effects. The ADD is usually expressed in terms of mg/kg-day or other mass/mass-time units.

Background sample - A medium-specific sample taken from a location where the chemicals present in that medium are assumed to be present as a result of natural sources.

Bias - A systematic error inherent in a method or caused by some artifact of the measurement system.

Biota - The plants and animals in a study area.

Chemical of potential concern - A chemical that is initially identified or suspected of being present at a site that may be hazardous to human health.

Chronic intake - The long term period over which a substance crosses the outer boundary of an organism without passing an absorption barrier.

Comparability - The ability to describe likenesses and differences in the quality and relevance of two or more data sets.

Contaminant concentration - Contaminant concentration is the concentration of the contaminant in the medium (air, food, soil, etc.) contacting the body and has units of mass/volume or mass/mass.

Deposition - The removal of airborne substances to available surfaces that occurs as a result of gravitational settling and diffusion, as well as electrophoresis and thermophoresis.

Detection limit - The minimum concentration or weight of a chemical that can be detected by a measurement instrument above background noise.

Distribution - A set of values derived from a specific population or set of measurements that represents the range and array of data for the factor being studied.

Dose - The amount of a substance available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism. The potential dose is the amount ingested, inhaled, or applied to the skin. The applied dose is the amount of a substance presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism). The absorbed dose is the amount crossing a specific absorption barrier (e.g., the exchange boundaries of skin, lung, and digestive tract) through uptake processes. Internal dose is a more general term denoting the amount absorbed without respect to specific absorption barriers or exchange boundaries. The amount of a chemical available for interaction by any particular organ or cell is termed the delivered dose for that organ or cell.

Dose-response relationship - The resulting biological responses in an organ or organism expressed as a function of a series of doses.

Duplicate - A second sample taken from the same source at the same time and analyzed under identical conditions to assist in the evaluation of sample variance.

Exposure area - The area of a site where a receptor is likely to come into contact with the chemical of concern.

Exposure duration - Total time an individual is exposed to the chemical being evaluated.

Exposure assessment - The determination or estimation (qualitative or quantitative) of the magnitude, frequency, or duration, and route or exposure.

Exposure concentration - The concentration of a chemical in its transport or carrier medium at the point of contact.

Exposure pathway - The physical course a chemical takes from the source to the organism exposed.

Exposure route - The way a chemical pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Exposure scenario - A set of facts, assumptions, and inferences about how exposure takes place that aids the exposure assessor in evaluating, estimating, or quantifying exposures.

Exposure - Contact of a chemical, physical, or biological agent with the outer boundary of an organism. Exposure is quantified as the concentration of the agent in the medium in contact integrated over the time duration of the contact.

Exposure duration - Length of time over which contact with the contaminant lasts.

General population - The total of individuals inhabiting an area or making up a whole group.

Geometric mean - The nth root of the product of n values.

Hot Spot - Location of a substantially higher concentration of a chemical of concern than in surrounding areas of the site.

Inhaled dose - The amount of an inhaled substance that is available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism.

Instrument detection limit - The lowest amount of a substance that can be detected by an instrument without correction for the effects of sample matrix, handling, and preparation.

Intake - The process by which a substance crosses the outer boundary of an organism without passing an absorption barrier (e.g., through ingestion or inhalation).

Intake rate - Rate of inhalation, ingestion, and dermal contact depending on the route of exposure. For ingestion, the intake rate is simply the amount of food containing the contaminant of interest that an individual ingests during some specific time period (units of mass/time). For inhalation, the intake rate is the rate at which contaminated air is inhaled. Factors that affect dermal exposure are the amount of material that comes into contact with the skin, and the rate at which the contaminant is absorbed.

Integrated Risk Information System (IRIS) - An EPA database containing verified RfDs, RfCs, slope factors, up-to-date human health and regulatory information on numerous chemicals.

Internal dose - The amount of a substance penetrating across absorption barriers (the exchange boundaries) of an organism, via either physical or biological processes (synonymous with absorbed dose).

Lifetime average daily dose - Dose rate averaged over a lifetime. The LADD is used for compounds with carcinogenic or chronic effects. The LADD is usually expressed in terms of mg/kg-day or other mass/mass-time units.

Limit of Detection (LOD) - The concentration of a chemical that has a 99% probability of producing an analytical result above background "noise" using a specific method.

Limit of Quantitation (LOQ) - The concentration of a chemical that has a 99% probability of producing an analytical result above the LOD. Results below LOQ are not quantitative.

Median value - The value in a measurement data set such that half the measured values are greater and half are less.

Method Detection Limit (MDL) - The detection limit that takes into account the reagents, sample matrix, and preparation steps applied to a sample in specific analytical methods.

Modeling - A mathematical description of an experimental data set.

Monte Carlo technique - A repeated random sampling from the distribution of values for each of the parameters in a generic (exposure or dose) equation to derive an estimate of the distribution of (exposures or doses in) the population.

Particulate - Solid material suspended in a fluid medium (air or water).

Pathway - The physical course a chemical or pollutant takes from the source to the organism exposed.

Pica - Deliberate ingestion of non-nutritive substances such as soil.

Population Variability - The variation in true pollution levels from one population unit to the next. Some factors that cause this variation are distance, direction, and elevation.

Potential dose - The amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin.

Practical Quantitation Limit (PQL) - The lowest level than can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions.

Precision - A measure of the reproducibility of a measured value under a given set of circumstances.

Probabilistic uncertainty analysis - Technique that assigns a probability density function to each input parameter, then randomly selects values from each of the distributions and inserts them into the exposure equation. Repeated calculations produce a distribution of predicted values, reflecting the combined impact of variability in each input to the calculation. Monte Carlo is a common type of probabilistic Uncertainty analysis.

Qualifier - A code appended to an analytical result that indicates possible qualitative or quantitative uncertainty in the result.

Random samples - Samples selected from a statistical population such that each sample has an equal probability of being selected.

Range - The difference between the largest and smallest values in a measurement data set.

Reasonable Maximum Exposure (RME) - The maximum exposure that could reasonably be expected to occur for a given exposure pathway at a site. The RME is intended to account for both variability in exposure parameters and uncertainty in the chemical concentration.

Receptor - An individual organism or species, or a segment of the population of the organism or species, that is exposed to a chemical.

Recreational/sport fishermen - Individuals who catch fish as part of a sporting or recreational activity and not for the purpose of providing a primary source of food for themselves or for their families.

Reference Dose (RfD) - An estimate (with uncertainty spanning an order of magnitude or more) of a daily exposure level for a human population, including sensitive subpopulations, that is likely to be without an appreciable risk of adverse health effects over the period of exposure.

Representativeness - The degree to which a sample is, or samples are, characteristic of the whole medium, exposure, or dose for which the samples are being used to make inferences.

Risk Characterization - The process of integrating the results of the exposure and toxicity assessments (i.e., comparing estimates of intake with appropriate toxicological values to determine the likelihood of adverse effects in potentially exposed populations.

Route - The way a chemical or pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Sample - A small part of something designed to show the nature or quality of the whole. Exposure-related measurements are usually samples of environmental or ambient media, exposures of a small subset of a population for a short time, or biological samples, all for the purpose of inferring the nature and quality of parameters important to evaluating exposure.

Sample Quantitation Limit (SQL) - The detection limit that accounts for sample characteristics, sample preparation, and analytical adjustments, such as dilution.

Screening-level assessments - Typically examine exposures that would fall on or beyond the high end of the expected exposure distribution.

Sensitivity - The capability of methodology or instrumentation to discriminate between measurement responses for quantitative differences in a parameter of interest.

Sensitivity analysis - Process of changing one variable while leaving the others constant to determine its effect on the output. This procedure fixes each uncertain quantity at its credible lower and upper bounds (holding all others at their nominal values, such as medians) and computes the results of each combination of values. The results help to identify the variables that have the greatest effect on exposure estimates and help focus further information-gathering efforts.

Slope Factor - A plausible upper-bound estimate of the probability of cancer response in an exposed individual, per unit intake over a lifetime of exposure.

Soil adherence - The quantity of soil that adheres to the skin and from which chemical contaminants are available for uptake at the skin surface.

Standard Deviation - The most common measure of the dispersion of observed values or results expressed as the magnitude of the square root of the variance.

Subsistence fishermen - Individuals who consume fresh caught fish as a major source of food.

Uncertainty - Uncertainty represents a lack of knowledge about factors affecting exposure or risk and can lead to inaccurate or biased estimates of exposure. The types of uncertainty include: scenario, parameter, and model.

95% Upper Confidence Limit (UCL) - A value that, when calculated repeatedly for different, randomly drawn subsets of site data, equals or exceeds the true mean 95% of the time.

Upper percentile - Values at the upper end of the distribution of values for a particular set of data.

Uptake - The process by which a substance crosses an absorption barrier and is absorbed into the body.

Variability - Variability arises from true heterogeneity across people, places or time and can affect the precision of exposure estimates and the degree to which they can be generalized. The types of variability include: spatial, temporal, and inter-individual.

Weight-of-Evidence Classification - An EPA classification system for characterizing the extent to which available data indicate that an agent is a human carcinogen. Recently, EPA has developed weight-of-evidence systems for other kinds of toxic effects, such as developmental effects.

Source: Taken in part from U.S. EPA (1997; 1992c).

ACRONYMS

ADD	=	Average Daily Dose
ADI	=	Acceptable Daily Intake
AIC	=	Acceptable Intake for Chronic Exposure
AIS	=	Acceptable Intake for Subchronic Exposure
APDR	=	Acute Potential Dose Rate
ARAR	=	Applicable or Relevant and Appropriate Requirement
ATSDR	=	Agency for Toxic Substances and Disease Registry
BCF	=	Bioconcentration Factor
CDI	=	Chronic Daily Intake
CLP	=	Contract Laboratory Program
CR	=	Contact Rate
CRDL	=	Contract-Required Detection Limit
CRQL	=	Contract-Required Quantitation Limit
CTE	=	Central Tendency Exposure
DL	=	Detection Limit
DQO	=	Data Quality Objectives
E	=	Exposure Level
FOB	=	Fibers and Organics Branch
HEAST	=	Health Effects Assessment Summary Tables
HI	=	Hazard Index
HRS	=	Hazard Ranking System
IDL	=	Instrument Detection Limit
IRIS	=	Integrated Risk Information System
IUPAC	=	International Union of Pure and Applied Chemists
K_{oc}	=	Organic Carbon Distribution Coefficient
K_{ow}	=	Octanol Water Partition Coefficient
LADD	=	Lifetime Average Daily Dose
LOAEL	=	Lowest-Observed-Adverse-Effect-Level
LOD	=	Limit of Detection
MDL	=	Method Detection Limit
ND	=	Non-detect
NOAEL	=	No-Observed-Adverse-Effect-Level
NOEL	=	No-Observed-Effect-Level
NPCD	=	National Program Chemicals Division
NRC	=	National Research Council
OPPT	=	Office of Pollution Prevention and Toxics
PCB	=	Polychlorinated biphenyl
PCDD	=	Polychlorinated Dibenzo-p-Dioxin
PCDF	=	Polychlorinated Dibenzofuran
PQL	=	Practical Quantitation Limit
PRG	=	Preliminary Remediation Goal
QA/QC	=	Quality Assurance/Quality Control
QAPjP	=	Quality Assurance Project Plan
QL	=	Quantitation Limit

RAGS = Risk Assessment Guidance for Superfund
RBC = Risk Based Concentration
RfD = Reference Dose (when used without other modifiers, RfD generally refers to chronic reference dose)
RfD_{dt} = Developmental Reference Dose
RfD_s = Subchronic Reference Dose
RI/FS = Remedial Investigation/Feasibility Study
RME = Reasonable Maximum Exposure
SDI = Subchronic Daily Intake
SF = Slope Factor
SQL = Sample Quantitation Limit
SVOC = Semivolatile Organic Chemical
TAL = Target Analyte List
TCL = Target Compound List
TEF = Toxicity Equivalency Factor
TEQ = Toxic Equivalency
TIC = Tentatively Identified Compound
TSCA = Toxic Substances Control Act
UCL = Upper Confidence Limit
VOC = Volatile Organic Chemical

Taken in part from U.S. EPA (1989 and 1992a)

APPENDIX A

PCB Disposal Rule

APPENDIX B

EFHB Excerpts

APPENDIX C

PCB Toxicity Assessment Document

APPENDIX D

References on Dermal Absorption, Transfer Rate, Etc.

APPENDIX E

Guidelines for Exposure Assessment